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MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

January 3, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC and CMS-1325-F
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B

Dear Dr. McClellan:

The Medical Group Management Association (MGMA) is pleased to submit the following comments in response to the final rule entitled the "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B," as published in the Nov. 21, 2005 *Federal Register*. We appreciate the Centers for Medicare & Medicaid Services' (CMS) outreach to the provider community and their willingness to participate in constructive dialogue to improve the Medicare program. We look forward to continuing our collaborative work on this and other administrative simplification issues. For these reasons, MGMA offers the following critiques and recommendations related to this rule, as outlined below.

MGMA, founded in 1926, is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

Due to the nature of pending congressional action that has significant ramifications on the Medicare provider community, MGMA strongly urges CMS to work with its provider partners and have a final rule ready for publication upon the President's signature of the Deficit Reduction Act of 2005. Following release, materials and software patches must be sent to carriers and fiscal intermediaries, clarifying how they will address provider questions and offer instruction for payment processing. Of utmost importance, MGMA seeks clarification on the retroactivity of the law, when and if

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passed, and how the agency is instructing its contractors to adjudicate claims received before the claims processing systems are revised. Additionally, ample and timely provider materials, written in easy-to-understand language, must be available at the same time to decrease provider uncertainty and misunderstandings during this transition. MGMA looks forward to partnering with CMS during this and other conversions.

Sustainable Growth Rate

The downward spiral of payment updates for providers paid under the Medicare physician fee schedule is prolonged for the fourth consecutive year with the 2006 projected cut of 4.4 percent. Without Congressional action, physicians would have been cut over 15 percent since 2001. If the current trend remains, providers will face difficult decisions as they evaluate the economic practicability of caring for Medicare beneficiaries. The economic viability of practices is further undermined by the widespread use of the Medicare physician fee schedule as a benchmark for private insurance reimbursement rates.

MGMA has conducted extensive surveys of medical practice costs for more than 50 years. MGMA-collected data indicate that the cost of operating a group practice rose by an average 4.93 percent per year over the last 10 years. In fact, between 2000 and 2004, MGMA data show that operating costs increased more than 17.9 percent. Medicare reimbursement rates for physician services have fallen far short of the increased cost of delivering quality services to Medicare payments. Agency-initiated administrative modifications can help mitigate the anticipated cuts for calendar year 2006 and beyond.

Definition of "physician services"
The statutory language of the Social Security Act that defines the payment update formula requires CMS to assess the allowed and actual expenditures of the Medicare program. MGMA maintains that the definition used by CMS for "physician services" in the sustainable growth rate (SGR) formula is inappropriate. MGMA believes this definition is incorrect due to the inclusion of the cost of physician administered outpatient prescription drugs.

A significant factor in the growth in Medicare expenditures has been the introduction of the program's coverage of costly new prescription drugs administered in the physician's office. Since the SGR base year, SGR spending for physician-administered drugs has more than doubled. These expenses reflect the acquisition of products rather than services rendered by a medical professional and therefore are different than "physician services." The inclusion of drugs in the definition of physician services is inaccurate and runs counter to CMS' stated goal of paying appropriately for drugs and physician services. MGMA asserts that the definition of "physician services," as required by the statute, does not include the cost of prescription drugs.

A separate definition of physician services clearly distinguishes physician administered outpatient prescription drugs from services rendered by physicians. CMS adopted this definition in the Dec. 12, 2002 "Inherent Reasonableness" rule (67 FR 76684). Plainly, the definition of physician services must be applied consistently for fair and equitable administration of the Medicare program. Furthermore, the recent proposed rule to reform the payment system for physician administered prescription drugs establishes a separate venue to address the utilization and cost of drugs. MGMA strongly urges CMS to remove prescription drug expenditures from the definition of "physician services" used to calculate the physician payment update factor.

MGMA understands that CMS has begun to explore the legal ramifications of removing physician administered outpatient prescription drugs from the definition of physician services and

appreciates CMS' willingness to do so. MGMA realizes that CMS continues to have concerns about the removal of these drugs from the formula on a retrospective basis; however, MGMA urges CMS to remove these drugs from the definition of "physician services" used in the calculation of the physician payment update factor.

Full impact of law and regulation

The current SGR calculation fails to adequately capture the impact of changes to laws and regulations as required by law. For example, although Medicare has new screening benefits, the formula fails to account for the downstream services that will result when the screenings reveal health problems. The same is true of the Medicare prescription drug benefit, which will unquestionably lead to more medical visits, and in turn will generate additional tests and care. The SGR does not account for this inevitable program spending.

Additionally, the impact of administrative coverage decisions is excluded from the SGR entirely even though those decisions may have as great an impact on patient demand for services as a statutory change. In this proposed rule, for example, CMS administratively proposes to extend screening glaucoma coverage to Hispanic patients over age 65. Such changes are likely to be highly beneficial for patients, but may contribute to negative reimbursement updates through the SGR calculation. MGMA believes CMS has the administrative authority to better account for the full impact of such changes to law and regulation, and vigorously urges CMS to assert this authority.

MEI calculation

Another component of the Medicare physician reimbursement formula that requires improvement is the Medicare Economic Index (MEI). The MEI was established in 1973 to reflect the rising cost of practicing medicine. However, the current MEI calculation is showing its age, and fails to incorporate all of the costs a physician group practice bears to care for patients. MGMA agrees with a recommendation by the Practicing Physicians Advisory Council made to CMS in 2004 that the MEI be expanded to reflect costs such as compliance with extensive new billing regulations, including hiring new staff and increased training for current staff to comply with expanding regulations. The MEI also should reflect steps taken to improve patient safety and include those additional costs not included in the MEI in 1973, but which clearly must be a part of the calculation today.

Additionally, the MEI must reflect the modern level of support staff. A particular concern to MGMA is that employee wages used in the MEI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. MGMA recommends that CMS work with other government agencies such as the Bureau of Labor Statistics and private organizations to identify other nationally collected data sources or to collaborate the development of survey methodology and data collection if no such source currently exists.

Resource-based Practice Expense RVUs

MGMA applauds CMS' decision to delay implementation of the new "bottom-up" methodology. MGMA welcomes the opportunity to continue to work with CMS in development of the new

practice expense (PE) values. MGMA appreciates CMS' willingness to listen to industry concerns regarding the availability of the fully implemented data. This data are not widely understood, and sample PE RVU value calculations were not accurate, causing a further lack of clarity.

Geographic Practice Cost Indices (GPCIs)

MGMA remains opposed to CMS' usage of inappropriate data sources to calculate the GPCIs. As we have articulated in the past, the very nature of the census data used to calculate the GPCI values renders the values outdated by the time CMS is able to use the information. The decennial collection of the census means that no new data will be available on a national scale until the 2010 census data is processed. Thus, although the statute mandates updating the GPCI values every three years, they are in essence updated every ten years. MGMA maintains that this is unacceptable. MGMA recommends that CMS work with other government agencies, including the Bureau of Labor Statistics and private organizations, to identify alternative data sources. Alternatively, CMS should work with the provider community and government agencies to identify an appropriately indexed data source to meet the statutory requirements.

Of particular concern to MGMA is that employee wages used in the GPCI formula do not capture highly skilled professionals now considered essential for the delivery of medical services. These professionals include nurse practitioners, physician assistants, certified nurse specialists, nurse midwives, certified registered nurse anesthetists, occupational therapists, physical therapists, certified practice managers, computer professionals, transcriptionists and certified coders. While it remains true that the 2000 census definitions of certain medical professionals are more expansive than the 1990 definitions, limited improvements result for the updated GPCI values. The wages of several prominent professions continue to be excluded, including physician assistants, occupational and physical therapists, certified practice managers, IT professionals, transcriptionists and certified coders. MGMA recommends that CMS revise the GPCIs to include these employees to ensure that the occupations used in the formula reflect the numerous categories of medical workers found in modern practices.

As in years past, the office rental indices used to calculate the practice expense GPCIs are based on the Department of Housing and Urban Development's (HUD) residential apartment rent data. While MGMA is sympathetic to the difficulty CMS has in identifying alternative sources for pricing medical office space, MGMA remains opposed to the use of residential, and not commercial data, for this purpose. Such use is inconsistent with the core objective of the Balanced Budget Act of 1997 to make Medicare resource based. MGMA suggests that CMS study whether actual physician office rental costs vary geographically in the same manner as the rental index currently used in order to validate the use of this proxy. Alternatively, MGMA again recommends that CMS work with other government agencies, such as the Bureau of Labor Statistics, to identify other nationally collected data sources and groups that are capable of collecting data, if no such source currently exists.

As noted in our previous comments, MGMA also highlights the findings of the General Accountability Office (GAO) in their March 2005 report on HUD estimates of fair market rents (GAO-05-342). The report identified major concerns raised by the HUD estimates, substantiating the level of inaccuracy reported by many MGMA members. The report also explains that HUD will soon use a new data source, the American Community Survey (ACS). It is important to note that ACS processes rates differently than HUD has in the past. With this impending data shift, MGMA urges CMS to work with HUD and the Bureau of Labor Statistics to determine whether

the values populating the GPCI calculations for medical practice rent are accurate and will meet the agency's needs once ACS data is adopted by HUD.

Contractor Pricing of Unlisted Therapy Modalities and Procedures

MGMA supports CMS' decision to use Medicare contractors to provide values for CPT codes 97039 and 97139, two unlisted codes with assigned RVUs. MGMA also applauds CMS for its willingness to work with specialty organizations to ensure that the appropriate payment for actual services provided.

Teaching Anesthesiologist

As noted previously, MGMA represents specialties practicing in numerous medical settings, including anesthesiology practices in teaching hospitals. Working with our Anesthesiology Administrators Assembly, MGMA understands that the payment policy for teaching anesthesiologists adopted in the 2004 final physician fee schedule [68 FR 63224] is inconsistent with payment policies for other teaching specialty, namely supervising teaching surgeons. MGMA applauds CMS' continued work with the American Society of Anesthesiology and continues to defer to the Society's recommendations for the Medicare policy on payment for teaching anesthesiologists.

Additionally, any change that CMS adopts for teaching anesthesiologist payment must be appropriately accounted for in the SGR calculation.

End Stage Renal Dialysis Related Provisions

ESRD-Composite Payment Wage Rate Index

Hospital Data Used

MGMA is concerned by the use of acute care hospital inpatient wage index data in the calculation of the End Stage Renal Dialysis (ESRD) Composite Payment Wage Rate Index. This index is used to determine payment to both hospital-based and independent ESRD facilities. Using only hospital data in this calculation implies that wages in hospital-based and ambulatory facilities are the same or similar in nature; however, no such determination has been made. In fact, the costs for hospital-based facilities and ambulatory centers vary greatly. The ESRD-Composite Payment Wage Rate Index needs to take into consideration wages paid in independent facilities, in addition to those paid in acute care hospital inpatient settings.

Use of Floor/Ceiling Values

In addition to a cut in physician reimbursement, CMS will remove the wage index floor over the course of a two-year period. ESRD facilities that have already received cuts during the transition to the average sales price drug reimbursement methodology will be further penalized. The removal of the wage index floor will result in a decrease in reimbursement in some geographic areas, causing facilities to have greater difficulty recruiting and retaining qualified personnel in the affected areas.

MGMA applauds the removal of the wage index cap, which will allow the payment formula to reflect the higher salaries required in higher cost localities. However, the budget neutrality

adjustment acts as a cap, preventing affected facilities from receiving the full benefits of this change.

Payment for Covered Outpatient Drugs and Biologicals

ASP Issues

MGMA has consistently expressed its concern that Medicare reimburse providers appropriately for both the cost of drugs administered in the outpatient setting and the cost of physician administration services. The MMA dramatically altered reimbursement in both of these areas, and MGMA remains extremely concerned about the adequacy of reimbursement levels.

Estimation Methodology for Lagged Price Concessions

MGMA remains skeptical of the quarterly update system of the average sales price (ASP). Drug acquisition costs fluctuate daily. This means that quarterly reimbursement rates leave practices with little or no cushion for volatility. Furthermore, MGMA, the American Medical Association and a number of medical specialty associations have found that the ability for physician practices to obtain discounts varied widely by specialty, geography and other factors. Thus, market-share and good negotiation skills may not be enough for practices to stay at or below the ASP rate.

Contrary to MGMA member reports, CMS continues to point to the MedPAC, Office of the Inspector General (OIG) and Government Accountability Office (GAO) studies that found practices able to obtain drugs at or below Medicare reimbursement rates. MGMA reminds the agency that these studies are not statistically valid and did not gather information from an adequate stratification of medical practices ranging from solo practitioners to large networks across the country. Nor did these studies address the acquisition cost discrepancy experienced by the various specialties that deliver the drugs.

For these reasons, MGMA recommends that CMS, in conjunction with MedPAC, the OIG and GAO, conduct a market-based survey to determine whether the ASP system is adequate to reimburse a majority of medical practices for their acquisition costs for Part B drugs, and report these findings to Congress. Additionally, MGMA recommends that CMS establish an exception policy whereby individual providers and practices that cannot acquire drugs at a rate that exceeds a percentage of the ASP+6 be able to quickly report the problem to the agency and seek reimbursement at the acquisition cost. MGMA believes that this is in the spirit of the reforms made in the Medicare Prescription Drug, Improvement and Modernization Act.

Price Concessions: Wholesaler Chargebacks

The proposed rule would have required drug manufacturers to calculate the ASP for direct sales of drugs independently from the ASP for all other sales subject to the ASP reporting requirement. Manufacturers would then calculate a weighted average of the direct sales ASP and the indirect sales ASP for submission to CMS. MGMA supports the withdrawal of the calculation revision as defined in the interim final rule due to the unclear advantage of using this new data source. MGMA encourages CMS to continue to work with drug manufacturers, wholesalers and the medical community to improve the data used in the ASP calculation.

Determining the Payment Amount Based on ASP

For the upcoming year, CMS will provide an additional payment to physicians and hospital outpatient departments to compensate for the additional resources needed to locate and acquire immunoglobulin (IVIG), as well as to prepare it for infusion. Stipulated in the interim final rule, carriers will reimburse providers for HCPCS code G0332 when billed once a day per patient in association with the provision of IVIG. MGMA is encouraged by CMS' awareness of provider difficulties obtaining IVIG at ASP+6 rates and willingness to administratively look for solutions. However, MGMA is very concerned with the implementation of this new code. According to the 2006 National Physician Fee Schedule Relative Value File carrier file last updated on the CMS Web site on Nov. 16, 2005, G0332 is not listed. MGMA hopes that a supplemental carrier transmittal will be issued that will allow for providers to be reimbursed on Jan. 1, 2006 for IVIG administration services. Furthermore, MGMA is disappointed by the delay in provider education materials being distributed on this new service. These materials must be made available several weeks before the beginning of the new year; not the holiday week between Christmas and New Years when many providers are out of the office.

The administration bonus for 2006 is a step in the right direction but not a permanent fix to the problem. MGMA members have responded to the initiative by indicating that the additional funds will help, but prices for both forms of IVIG in powder and liquid form rose in 2005 while reimbursement declined. MGMA remains concerned that the data being sent to CMS for use in the ASP is not accurate and does not reflect what the average provider of Part B drugs pays for their supply. Only a market-based study can determine whether the ASP reflects current market rates.

The competitive acquisition program (CAP) may offer a viable alternative for providers who are unable to obtain IVIG at or below the ASP+6 rates. However, the program as proposed is not a viable option for IVIG providers as it is overly burdensome and IVIG is excluded from the national drug category. Therefore, MGMA recommends that CMS continue to monitor the need of providers to have options for accessing IVIG while reducing the administrative burdens of the CAP.

Although not specifically covered in the 2006 Medicare physician fee schedule interim final rule, MGMA would like to comment on our grave concerns regarding the crossover of the Part B and D programs for physician-administered drugs. As clarified by the agency in several rules and provider education materials, drugs covered by Part D may be, in some instances, superceded by coverage decisions under the Part B program. For instance, several psychotropic drugs are addressed by local coverage decisions and in these jurisdictions will be reimbursed under Part B. Those regions without the same or similar decisions will cover the same drug under the Part D program. MGMA is troubled by the lack of clear information on this crossover and very concerned that providers and beneficiaries will be unable to identify under which program they should seek reimbursement. MGMA recommends that CMS establish a national online database that will identify drug coverage by region and program.

Payment for Drugs Furnished During CY2006 in Connection With the Furnishing of Renal Dialysis Services if Separately Billed by Renal Dialysis Facilities

The June 2005 Medicare Payment Advisory Commission (MedPAC) Report to Congress recommended that CMS standardize the reimbursement calculation for dialysis drugs rendered in ambulatory and hospital-based facilities. MGMA believes that a final rule establishing a

standardized reimbursement calculation for these drugs is premature because the appropriate data is not currently available. Instead, CMS should continue to calculate the add-on payment using the methodology currently in place for both types of facilities.

Additionally, the reimbursement for ESRD drugs under the ASP model exposes nephrology practices and dialysis patients to the dire issues faced by oncologists, rheumatologists, urologists and others, struggling to continue offering drug services to their Medicare patients. MGMA urges CMS to track reimbursement rates and actual acquisition costs by the dialysis community in both the ambulatory and facility settings. MGMA recommends that CMS quickly offer the competitive acquisition program as a viable alternative for nephrology practices.

Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B

On Aug. 3, CMS suspended the vendor bidding process for the competitive acquisition program (CAP), thus delaying implementation of the interim final rule. Following the brief delay, vendors were encouraged to submit their bids by Dec. 21. It is unclear at this time whether or not CMS received any adequate bids for the CAP. The following comments highlight a number of important concerns regarding the program as outlined in the various rules, whether or not a successful bidder will be identified.

Process for Adding NDCs Within an HCPCS Code in an Approved CAP Vendor's Drug List

MGMA appreciates CMS' effort to provide ample notice to providers and requiring at least 30 days notice of changes to CAP vender drug lists. However, MGMA remains skeptical that providers would be aware of modifications to the plan with variations in mailing requirements, forwarding of information from billing offices and departments and other internal handling. Therefore, MGMA recommends that (1) the notice be at least 45 business days from the date of mailing, (2) CAP vendors be required to post information to their individual Web site and CMS post changes to the CAP Web page on the CMS Web site and (3) CAP vendors establish a voluntary email list for participating providers and/or their administrators and staff for timely notices of changes in their program. MGMA believes that these three essential elements be required of any and all modifications to the CAP program.

Other Issues Related to Drugs Supplied Under the CAP – (iii) Physicians Regulatory Issues Team (PRIT) Drugs

We are disheartened by CMS' refusal to disclose the list of Part B drugs that providers report acquisition problems. By disclosing the list, the provider community can assist CMS in identifying which drugs pose the biggest problems and where regional fluctuations exist. Without the list, MGMA believes that the problems experienced by providers, evidenced by the PRIT list, underscore the immediate need for a market-based survey of real-time acquisition costs for Part B drugs by solo practitioners and group practices of all sizes across the nation. Until a broad-based study is commissions, CMS and other lawmakers will continue to hear antidotal evidence of problems and no real concept on how to solve the issues raised by frantic providers.

Vendor/Bidding Issues – Approved CAP Vendor Requirements/Call Center Hours of Operation

The proposal put forth by CMS for vendors to have call centers and be available for reasonable hours of operation is heartening to MGMA and our providers. We encourage vendors to offer varying technological vehicles to contact their participating providers and beneficiaries. As noted above, we recommend that in addition to the call center requirements, CAP vendors establish: (1)

web pages for CAP providers and patients, (2) a voluntary listserv for timely notices of changes to the CAP program, (3) an email address where providers can email their written inquiries as an alternative to calling into the call center, and (4) that CMS establish a reasonable amount of time for CAP vendor response to email inquires. We believe that these additional requirements are not overly burdensome or expensive and are in line with CMS' requirements of itself and other contractors working directly with Medicare providers.

Operational Issues – Timing of Approved CAP Vendor Billing/Payment of Claims

In this rule and the several that precede it, CMS states that approximately 80 percent of Medicare patients have supplemental insurance. MGMA seeks clarification on the source of this data and a break down of payer type (e.g. Medicaid, Medigap, etc.).

Furthermore, MGMA wishes to highlight the complexities and inconsistencies of the crossover claim system and the coordination of benefits process. "Because approximately 80 percent of beneficiaries have a Medicare supplemental policy that includes coverage for Part B cost sharing, their coinsurance and deductible payments should be made automatically in most cases by their supplemental insurer under the coordination of benefits process" (70 FR 70255). However, we do not believe that the process is currently as smooth as described in the final rule. MGMA members report widespread inconsistencies with the forwarding and processing of claims by supplemental insurers. For medical group practice administrators, this results in prolonged accounts receivables and labor-intensive accounts handling. Therefore, MGMA recommends that CMS investigate the status of the coordination of benefits system and work with the provider community to improve the crossover process. In turn, this systems repair will benefit CAP vendors and the Medicare provider community.

Additionally, CMS notes that CAP vendors will be able to verify beneficiary supplemental coverage by contacting the supplemental insurer directly. MGMA is frustrated by this statement due to the availability of the X12 4010 A1 270/271 electronic transaction under the Health Insurance Portability and Accountability Act that can easily facilitate this inquiry. MGMA recommends that CMS quickly adopt this transaction system-wide to enable cost-effective implementation of the CAP and urges the agency to encourage its partners, including supplemental insurers, to adopt and offer this transaction to providers.

Beneficiary Issues – Coinsurance

MGMA appreciates CMS' clarification regarding when vendors must disclose information to beneficiaries about their financial assistance program(s). However, we wish to make clear that vendors are required to educate all new beneficiaries about the program's availability and request that vendors share information about these programs any time a Medicare patient seeing a CAP provider calls in regarding their bill. For many Americans, it is a difficult task to ask for help, and the simple fact that assistance is available should be readily apparent to any and all patients. Yet, MGMA remains concerned about instances where Medicare beneficiaries in the "gray area" are unable to make payments on their coinsurance but too affluent under the financial guidelines of the assistance program to qualify. While this is a difficult situation, MGMA urges CMS to standardize the financial qualification standards for the assistance programs offered to CAP beneficiaries. Additionally, MGMA strongly urges CMS to consult with these programs (and/or their host CAP vendor) to ensure that 15 business days is ample time to process a beneficiary application and reimburse the CAP vendor.

Beneficiary Issues – Advance Beneficiary Notices (ABNs)

The clarifications in the rule on the provider and CAP vendor's responsibilities to obtain an ABN and the possibility for collaborative arrangement between the two actors is encouraging to our association. These statements were imperative for a clearer understanding of how the CAP will be administered once implemented. With this new understanding, MGMA seeks further clarification that vendors employing blanket ABNs will be treated the same as providers: in addition to expulsion from the CAP program, unscrupulous vendors may be unable to conduct business with the Medicare and Medicaid programs and be scrutinized under the False Claims Act. For this reason, MGMA urges CMS to require CAP vendors to submit drug claims with the ABN modifiers and monitor their utilization of these notices. Additionally, MGMA requests that the ABN decision tree made available on the CMS Web site be updated to reflect instances where provider partners and CAP vendors should seek a beneficiary's signature to an ABN.

Physician Election Issues and Education – Group vs. Individual Participation in CAP

The final 2006 Medicare physician fee schedule rule continues the false policy that if one physician in a group practice enrolls in the CAP program, all physicians in the group must adhere to the participation decision of the individual. This highly discriminatory policy places solo practitioners in a much better position than group practices when it comes to evaluating CAP enrollment. MGMA believes that the participation decision should be determined on an individual physician level and should not be attributed to a whole group.

Also of significance, this is the only Medicare enrollment decision where the decision of an individual provider binds the entire group practice. The participation decision to accept assignment and enroll in Medicare is made on an individual basis and providers may bill under a group number regardless of their participation status. Thus, MGMA continues to strongly recommend that CMS withdraw the group practice provision found in 42 CFR 414.908(a)(4).

Physician Election Issues and Education – Participating CAP Physician Opt-Out for Non-Payment of Coinsurance

We believe that the policy adopted in this rule for the mid-year opt-out of CAP providers when vendors refuse to ship drugs to an individual patients is valid protection for patients and providers alike. MGMA hopes that when the CAP expands to more categories that this policy will enable CAP providers to withdraw from the entire program when a patient is expelled, so that the provider can address administrative burdens related to ordering drugs from two or more sources versus the likely single-source that the CAP should offer.

Brief Summary of Comments We Are Not Addressing

MGMA anxiously anticipates the next rule, which we strongly recommend must be open to public comment to determine the rule's impact on the provider and patient communities. Therefore, MGMA recommends that any final rule should be published as an interim final rule with comment.

Private Contracts and Opt-Out Provision

MGMA applauds CMS for recognizing concerns and establishing regulations, as well as for clarifying opt-out requirements. The final rule establishes regulations that address the situation where a provider who has opted out of the Medicare program fails to maintain the requirements

of their status and goes undetected by carriers. In particular, the regulations would provide medical practitioners who have opted out of the Medicare program the opportunity to correct the violation within 45 days. MGMA believes 45 days is not a sufficient amount of time in which to correct a failure to maintain opt-out conditions. CMS should consider extending this time period to a minimum of 60 business days. MGMA thanks the agency for noting the standardized language to be used for violation notices. MGMA seeks the opportunity to continue working with CMS in order to develop clear guidelines to assist carriers in executing timely notice of opt-out violation.

Multiple Procedure Reduction for Diagnostic Imaging

CMS will reduce payment for the technical component for multiple imaging services performed on contiguous body parts. There will be a total decrease of 50 percent over a 2-year period. MGMA is concerned about the arbitrariness of a 50 percent reduction. It does not appear that CMS is basing the 50 percent reduction on sufficient and sound data. Before CMS makes a policy change that would severely impact certain specialties, MGMA urges the agency to reconsider the 50 percent figure to ensure its equity.

Furthermore, it is unclear at this time whether Medicare claims processing systems will permit diagnostic imaging services subject to the reduction to be billed globally. As previously experienced with physician scarcity and health professional shortage area payments, global payments for services with technical components that are treated differently caused major system errors and necessitated that these codes to be unbundled for several months. MGMA seeks clarification whether these services may be billed globally, and prefers that practices be able to bill globally.

Therapy Cap

CMS notes that, absent a legislative change, the effective date for payment caps for outpatient physical therapy, speech-language pathology and occupational therapy is Jan. 1, 2006. MGMA recognizes that CMS does not have authority to change this circumstance but urges the agency to prepare for the possibility that Congress will take no action. MGMA encourages the agency to design a method for providers to ascertain whether or not a given beneficiary has exceeded the applicable cap. MGMA is concerned that little information has been made available to providers regarding the procedures for implementation. Often times, Medicare beneficiaries change their living arrangements during the year, moving between carrier localities. Information on the amount paid for therapy services to a given beneficiary in all locations must be readily accessible. This will enable carriers to inform providers whether or not the appropriate cap has been exceeded.

MGMA continues to recommend that CMS use the system it prepared for therapy implementation in 2003 that would indicate for each beneficiary the dollar value of therapy services that have been applied towards the cap. These tracking notices would be included on patient and provider copies of the Medicare Summary Notice. Furthermore, MGMA recommends that this information be included in the functionality for the standardized electronic eligibility transaction (X12 4010 A1 270/271) implemented by Medicare and should track therapy services across carrier jurisdictions. Lastly, clarification on the billing policies for services provided to beneficiaries who have exceeded the cap should be issued to patients and providers. Of important consideration, no updated provider education materials have been distributed to re-educate providers on how cap notification will take place. Since it is already after the first of the year, it is imperative for CMS to immediately issue a provider education article on the therapy caps.

Screening Services for Glaucoma

MGMA is appreciative of the addition of preventative care to the categories of services covered by Medicare. This is a welcome opportunity for providers to help patients obtain treatment before the prognosis is a foregone conclusion. MGMA looks forward to working with the agency to educate the provider community on this new covered service. As noted in previous comments, MGMA urges CMS to work with the Secretary to add information on beneficiary eligibility for all covered screening tests to the X12 4010 A1 270/271 eligibility transaction.

It is important that the additional coverage of glaucoma screening services for Hispanic patients must be appropriately accounted for in the SGR calculation. As previously explained, MGMA believes CMS has the administrative authority to better account for the full impact of such changes to law and regulation, and forcefully urges CMS to assert this authority.

Physician Referrals for Nuclear Imaging Services

Under the final rule, CMS includes nuclear medicine as a designated health service (DHS) for purposes of the federal prohibition against self-referral. As MGMA requested in our previous comments, we commend the agency for attempting to minimize the impact on medical group practices by delaying implementation of the provision by one year.

However, we are troubled by CMS' apparent focus on physician self-referral as the cause of the growth in imaging. Rather than hastily conclude that the growth in office-based imaging is due to "inappropriate" referrals, MGMA urges CMS to carefully consider other factors that have contributed to the growth.

Site of Service Shift

MGMA encourages CMS to further examine the shift in site of service as a major factor in growth in imaging services conducted in physicians' offices. Although MedPAC's 2005 report to Congress acknowledged that roughly 20 percent of imaging growth is due to the shift of imaging services from the hospital to the outpatient setting, the shift is not accounted for in MedPAC's comparison of growth in imaging services. This presents a misleading interpretation of the amount of growth in imaging services.

Consistent with results reported by MedPAC, it appears that nuclear medicine, along with other advanced imaging procedures, has grown faster than other imaging services. However, an analysis by the Lewin Group showed that, without accounting for shift in site of service, growth in nuclear imaging and magnetic resonance imaging (other than of the brain) is overstated by a third. When physicians must refer their patients to a hospital or imaging facility for needed tests, the process itself can increase costs to both Medicare and patients. The referral can result in as many as three or more appointments and visits – one to see the physician and learn an image is needed, a second to have the image taken and then a follow-up appointment and visit to the referring physician to receive the treatment plan based on the image. By reducing the number of visits, the shift to in-office imaging could directly reduce costs to both patients and Medicare, while increasing convenience and improving the timeliness of subsequent diagnosis and treatment.

Advances in Technology

Imaging technology has become more widely dispersed among specialists. Much of the scientific advancements in medical imaging are due to the development and refinement of imaging modalities by physician specialists, all in an effort to facilitate the adoption of medical imaging technology to achieve better patient care. Physicians rely on imaging to avoid exploratory surgeries, detect diseases and complications earlier, and to help prevent unnecessary hospitalizations. Growth in the use of imaging services is, in part, reflective of growing applications for these technologies.

Although CMS acknowledges the role of technological innovation in the growth of imaging services, MGMA does not believe that the role of technology is adequately factored in the analysis of imaging growth, particularly the issue of substituting one treatment or diagnosis method for another. The MedPAC report made little mention of the value that medical imaging has brought to patients, physicians or the health care delivery system as a whole. An analysis is needed to evaluate the incremental costs of procedures in relation to their incremental health benefits.

Physician Self-Referral

MGMA is very concerned that calculations made by CMS and MedPAC fuel the inaccurate perception that growth in medical imaging services is due to inappropriate physician referrals. With the documented shift in site of service, physicians are performing more medical imaging tests in their offices, and the number of imaging services billed under Part B is increasing.

MedPAC's report fails to conclude what growth in medical imaging, if any, is due to inappropriate in-office utilization for financial gain. In fact, no credible body has been able to quantify whether and to what degree imaging performed in an office setting is inappropriate. Unfortunately, some have begun to equate legally permissible referrals with inappropriate utilization of imaging services.

Central to the argument that self-referral is a significant cost-driver is the idea, supported by MedPAC, that physicians will automatically over-utilize imaging services to increase their practices' revenue and income. However, studies demonstrate that physicians order more images when they have access to on-site imaging equipment, even when they do not own it and have no financial incentives to do so. Evidence suggests that, even in the absence of financial incentives, the mere availability of imaging technology will lead to increased utilization because the image can be taken and interpreted immediately and can be used for patient care decisions all in a single visit. (R.P. Strasser, M.J. Bass, M. Brennan, "The effect of an on-site radiology facility on radiologic utilization in family practice," *Journal of Family Practice* 1987; 24:619-623. K.K. Oguz, D.M. Yousen, T. Deluca, E.H. Herskovitz, N.J. Beauchamp, "Effect of emergency department CT on neuroimaging case volume and positive scan rates." *Academic Radiology* 2002; 9:1018-1024.)

Oncology Demonstration Project

While MGMA commends CMS for its recognition of the additional work associated with reporting data and the need to pay providers for this work, MGMA remains concerned about the impact of these payments on beneficiaries. As noted in discussions with CMS officials, beneficiaries are responsible for paying co-insurance of 20 percent. This means that any

additional payments made to providers increase co-insurance payments of beneficiaries, adding to the beneficiaries' ever-increasing financial burden.

According to the final rule, the pilot program is limited to two specialties, hematologists and oncologists. However, some of the patients with diagnoses addressed in the initiative may be treated by physicians specializing in other areas of medicine. Physicians may have one specialty, such as gynecology or urology, as a primary designation and have oncology or hematology as a secondary designation. The project's design leaves it unclear as to whether these physicians are eligible to participate in this initiative. While subsequent MedLearn Matters provider education articles clarify this billing situation, these coverage issues are not addressed in regulation. Thus, MGMA urges CMS to consult with the affected specialty societies and be inclusive of other specialties involved in the treatment of cancer patients the opportunity to participate in the demonstration project.

Physician Voluntary Reporting Program

As noted above, CMS has recognized through the creation of billable G-codes for the oncology demonstration project that additional work is created when physicians are required to report data. While the two programs are similar in nature, the recently announced Physician Voluntary Reporting Program (PVRP) contains no such recognition. Instead, participating practitioners are expected to voluntarily provide data without reimbursement.

MGMA fully supports initiatives designed to improve the quality of medical care. However, this program and its associated burdens come at a time when providers are facing average cuts of 4.4 percent in Medicare reimbursement rates for the care of Medicare beneficiaries. The design of the PVRP fails to take into account these cuts, as well as the numerous additional costs generated by the data reporting.

The PVRP will create added burdens for group practice staff, such as increased staff time and education. Staff time will increase in order to collect information for the designated performance measures. In order to obtain this additional staff time, providers will need to either increase the size of their staffs or increase the number of hours worked by their staff. Both options contribute to increasing practice overhead. Also, staff and physicians will need to be educated about the PVRP and trained on the collection of appropriate data, further increasing overhead costs.

Officials have argued that shifting from paper recordkeeping to using of electronic health records (EHRs) will decrease health care spending; however, the data indicates otherwise. MGMA and University of Minnesota recently published a study that found practices with EHRs spend, on average, $33,600 per FTE physician and approximately $1,500 per month in associated maintenance charges. A number of practice administrators participated in a focus group on the proposed PVRP held at the MGMA Annual Conference in Nashville, Tenn. Of the participating administrators who have EHRs in their offices, all responded that they would have difficulty reporting the specified data without spending resources over and above what the practices have already expended.

By and large, practices do not have the expertise in-house to make the extensive revisions to software that would be required to collect the required G-codes. In order for these modifications to be made, providers would need to contract with their software vendors for updates to the software. The amount of both time and money required to complete the modifications is significant. Participants of the focus group felt that, regardless of the cost, it was unrealistic to expect that these changes could be made by the vendors within the next year based on their

experiences with the Health Insurance Portability & Accountability Act. These same administrators also indicated that, in order to participate in the PVRP, they would have to revert back to using paper medical charts and claims if not provided with enough time to obtain the necessary updates.

Another issue raised by practice administrators is the difficulty associated with data collection from services performed in a hospital setting by an office-based provider. Providers have little means of ensuring that orders placed on a hospital chart are, in fact, followed. Practice administrators have little or no access to hospital charts to collect necessary data or to ensure the accuracy of these charts. To hold group practices and/or physicians accountable for data that they have little control over or access to would be inappropriate.

CMS is clearly interested in pursuing quality of care measurement initiatives, as evidenced by the 2005 chemotherapy demonstration project, the 2006 oncology demonstration project, and the PVRP. It is unfortunate that CMS has opted to continue to implement such initiatives prior to the release of data from the chemotherapy demonstration project currently in operation. CMS and others in the medical community are left to make decisions on these new initiatives without learning from the current project. Before designing new demonstrations requiring providers to report data, CMS needs to make available data from the chemotherapy demonstration project, so the medical community can examine the processes used in the collection of data and analyze the implications of that information, including any resulting complications.

For instance, practice administrators participating in the focus group raised the issue of third-party payer recognition of the proposed G-codes. Where Medicare is a secondary payer and an applicable G-code is recorded, some administrators participating in the chemotherapy demonstration project found that claims would be rejected for failure to comply with the guidelines of the primary private payer. Delays of up to three months have been reported for payment of such claims; yet, the PVRP does not address this problem. Instead, CMS continues to rely on the same problematic data collection method without proposing a remedy or working with the private insurance industry to reduce the number of claims rejected as a result of these initiatives. The chemotherapy demonstration project needs to be examined for weaknesses in order to develop an effective and less burdensome method of data reporting.

While MGMA supports efforts to improve the systemic quality and safety of medical care, MGMA has concerns about the current ability to implement a system-wide reporting program in the ambulatory setting prior to the widespread availability of appropriate technology, the analysis and distribution of data from related efforts, and the elimination of resulting financial burdens. The current design of the PVRP does not address any of these concerns. Because of this, MGMA urges CMS to delay implementation of this program until these issues have been remedied.

Other Medicare program policies

MGMA's core purpose is to improve the effectiveness of medical group practices and the knowledge and skills of the individuals who manage and lead them. As such, MGMA are intimately involved in the education and direction of practice managers on Medicare billing and coding rules. MGMA continues to question the implementation of certain provisions under the MMA and other general policies.

Physician Scarcity Area and Health Professional Shortage Area Bonus Payments

MGMA has received reports from members that physician scarcity area (PSA) and health professional shortage area (HPSA) bonus payment remittances are sent to providers by carriers and MA plans on an inconsistent basis. These remittances allow practices to track exactly what it is they are being reimbursed for, as well as to ensure that they are submitting qualifying claims correctly. MGMA recommends that CMS require carriers and MA plans to send PSA/HPSA bonus payment remittances. These remittances should identify the provider and the service to which the bonus payment applies. One possible method of making these remittances available would be through the new Medicare Remit Easy Print (MREP) program.

Centers for Medicare & Medicaid Services Web site

In mid-December, CMS launched its revamped Web site, which was touted as being more "user-friendly." While MGMA staff and members may argue with that assessment, one thing is clear: all of the URLs included in the final 2006 Medicare physician fee schedule are now erroneous. MGMA strongly recommends that CMS issue an addendum or correction sheet so that members of the medical community may easily find former links on the new online CMS portal. We also recommend that CMS work with MGMA and other associations to update and improve the provider pages that the agency developed to ease our individual memberships' use of the online system.

MGMA appreciates your consideration of these comments and looks forward to collaborating to educate medical group practices on the numerous Medicare program changes. If you have any questions, please contact Jennifer Searfoss Miller in the Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and Chief Executive Officer

American Dietetic Association
Your link to nutrition and health.[sm]

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Policy Initiatives and Advocacy
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Washington, DC 20036-3989
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January 3, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
7500 Security Lane
Baltimore, MD 21244-8017

RE: 42 CFR Parts 405, 410, 411, 413, 414, 424, 426 [CMS-1502-FC].
Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006.

Dear Dr. McClellan:

The American Dietetic Association (ADA) appreciates this opportunity to re-affirm our comments on the Notice of Final Rule for the CY 2006 Physician Payment Schedule published November 21, 2005 (70 FR 70116) . We urge you to consider this information as you refine the Final Rule for CY 2006 and initiate procedures to revise methodology for relative values for the following year's rule.

The ADA represents nearly 65,000 food and nutrition professionals working to improve the nutritional status of Americans. As primary prevention, strong evidence indicates that nutrition helps promote health and functionality and affects each individual's quality of life. As secondary and tertiary prevention, medical nutrition therapy (MNT) is a cost-effective disease management strategy that lessens chronic disease risk, and which slows disease progression and reduces symptoms. Medicare Part B covers MNT provided by registered dietitians (RDs) for diabetes and chronic renal disease.

Telehealth for Individual MNT

ADA supports the final rule decisions to add individual MNT to the Medicare list of services that can be provided via telehealth, and recognize registered dietitians (RDs) and nutrition professionals as qualified healthcare professionals who can submit claims for individual MNT provided via telehealth. ADA welcomes the opportunity to assist CMS in educating Medicare RD providers on telehealth services and to inform and encourage physician practitioners and beneficiaries of this new service delivery option.

PE Methodology and Elimination of the Non-Physician Work Pool
ADA agrees with CMS' decision to withdraw the entire PE methodology proposal and to refine the process for the CY 2007 proposed rule.

We ask to participate in the process as a full partner when CMS considers how to revise the methodology to calculate CPT code relative values. When CMS convenes a meeting with interested medical societies to discuss the direct and indirect PE methodology and elimination of the non-physician work pool, as well as meet individually with groups to discuss their particular concerns, ADA representatives need to cover our unique experience and knowledge along with the other interested medical societies. We also request to meet separately with CMS to discuss the medical nutrition therapy CPT code RVUs, including the direct and indirect PE inputs for the codes.

The current methodology and the proposed bottom-up methodology for MNT services fail to appropriately recognize RD work. With the proposed CY 2006 RVUs for MNT CPT codes, the agency once again has overlooked the intent of Congress regarding the implementation (and payment) for medical nutrition therapy services. In particular:

- *MNT code PE inputs are not valid.*
  RD work should be fully recognized and accounted for in the code RVUs.
  The current direct inputs do not accurately reflect the RD's full clinical labor and professional service that is required to provide MNT. The inputs fail to represent the RD's pre-, intra-, and post-work times to provide this service as the current values significantly underestimate, or omit certain pre- and post-service activities.

  ADA recommends PE time be allocated consistently within the three MNT codes for pre-services, such as reviewing medical records and laboratory data, equipment set-up, and other clinical activities (greeting the patient, treatment room set-up); and for post-services such as dismantling and storing equipment and educational materials such as food models; documentation and conducting follow-up communications with the referring physicians, patients and family members as appropriate and necessary. CMS has not accurately represented these activities in the direct input data used to calculate the MNT RVUs.

  PE data that ADA discussed with the AMA PEAC in February 2005 indicates that the following minutes of clinical labor are accurate:

  - 39 minutes total clinical labor time, including RD professional work for 97802 and 97803 per unit code;
  - 28 minutes total clinical labor time, including RD professional work for 97804 per unit code.

  These work data are significantly different from the arbitrary direct input values that CMS has used in the proposed PE calculation of RVU for the MNT codes -- 25 minutes 97802; 22 minutes for 97803, and 9 minutes for 97804. (See accompanying table).

- *The RVUs for initial MNT (97802) and follow-up MNT (97803) should be the same.*
  Since the MNT codes are time-based, the complexity and amount of time spent completing the pre-, intra-, and post-service times will be reflected in the number of

units used for each code. Therefore, the four-minute difference that the agency currently used in the direct PE values for determining the total RVUs is not appropriate. Both initial and follow-up MNT for individual encounters should have the same direct PE RVUs.

- *CMS should pay RDs and qualified nutrition professionals 100% of the MNT code RVUs or pay 85 percent of designated physician codes.*
  While current policy is inconsistent with the authorizing statute, it also lacks intellectual integrity. In the agency's determination that there is no physician work for MNT services, and its policy to take 85 percent of the physician fee schedule values for the MNT CPT codes, the agency has created an unfair payment anomaly towards registered dietitians and nutrition professionals who provide and bill for the services using the MNT CPT codes. If the agency continues to support the premise that there is no physician work for the MNT codes, this 'double discount' can be corrected by paying RDs 100% of the physician fee schedule.

  Alternatively, there is external support for a far more transparent approach to MNT RVUs. AMA indicates in the CPT 2005 publication, "for medical nutrition therapy assessments and/or intervention performed by a physician, see Evaluation and Management or Preventive Medicine service codes." If CMS believes the MNT statute for payment must be followed, then the agency should base the RD payment rate on 85% of the total physician RVUs for these codes (eg. E&M code 99203). CMS has established a precedent of paying a percentage of the physician fee schedule for codes used by other non-physician practitioners. For example, social workers, certified nurse midwives, physician assistants, and certified nurse specialists are paid a percentage of the physician's fee schedule when providing services that otherwise would have been performed by the physician. The payment amount is based on the physician code to provide the service, not other non-physician practitioner codes for the service.

- *CMS should establish work RVUs for MNT codes provided by RDs.*
  ADA asks the agency to work with our professional association to determine appropriate values and methodology that accurately reflects the professional work of RDs for MNT services.

  If a work RVU cannot be established, ADA asks CMS to consider establishing a new PE category that specifically references the professional's work effort. This would be a separate calculation to the current PE that accounts for clinical labor to support the RD in providing MNT services.

Physician Liability Insurance (PLI) Calculation for RDs

ADA agrees with CMS and the PLI workgroup's decision that nonphysician professionals, such as RDs, incur PLI costs similar to the lowest cost physician specialty; the lowest current risk factor of 1.0. While ADA realizes that CMS was unable to identify all Medicare providers in the proposed and final rule, we note that reference to liability insurance for registered dietitians continues to be omitted in the agencies' comments.

Recognition of RD Medicare Providers by CMS

In closing, in future Federal Register notices and general communications that relate to Medicare Part B providers, ADA urges the agency to include registered dietitians in the printed list of Medicare Part B providers. RDs were omitted in all tables included in CMS-1502-P and CMS-1502-FC, in the list of providers eligible to "opt-out" of Medicare, and other references to

Medicare Part B providers in the proposed rules for the CY 2006 physician fee schedule (70 FR 45764).

ADA looks forward to partnering with CMS in the development of the RVUs for CY 2007 final rule and education on new changes for the 2006 calendar year. Please do not hesitate to call Mary Hager, PhD, RD, Senior Manager, Regulatory Affairs, (202) 775-8277, ext. 1007 or Pam Michael, Director of Nutrition Services Coverage Team, 312-899-4747, with any questions or requests for additional information.

Best regards,

Pam Michael, MBA, RD
Director of Quality, Outcomes and Coverage

Mary H. Hager, PhD, RD
Senior Manager, Regulatory Affairs

CMS PE inputs

2006 NPRM labor cost inputs (excerpt)

HCPCS	Source	CPEP	Staff Type	Description	Rate	Pre-Time NF	Intra-Time NF	Post-Time NF	Pre-Time F	Intra-Time F	Post-Time F	Valued NF	Valued F
97802	HCPAC	RUC	L043B	Registered Dietician	0.43	3	15	7	0	0	0	Y	Y
97803	HCPAC	RUC	L043B	Registered Dietician	0.43	3	15	4	0	0	0	Y	Y
97804	HCPAC	RUC	L043B	Registered Dietician	0.43	1	7	1	0	0	0	Y	Y

Source: 42 CFR Parts 405, 410, 411, 413, 414, 426 [CMS-1502-P].
Medicare Program: Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006- Proposed Rule

AMERICAN COLLEGE OF GASTROENTEROLOGY

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January 3, 2006

RECEIVED - CMS
1/4/06 3:32

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1502-FC
Room 445-G, Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Comments on Medicare Program – CMS-1502-FC; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; 42 CFR Part 405, 410, 411, 413, 414, 424 and 426

The American College of Gastroenterology is pleased to provide these comments with respect to CMS' final rule, published in the Federal Register on November 21, 2005, on revisions to the payment policies under the Medicare Part B Physician Fee Schedule (Calendar Year 2006); specifically:

1. Practice Expense Surveys and Changes to Practice Expense RVU Methodology;
2. Sustainable Growth Rate (SGR) Formula and Physician Payment Level for CY 2006;
3. Site-of-Service Differential for Gastrointestinal Endoscopic Procedures;
4. Declining Reimbursements Hinder Utilization of Colorectal Cancer Screening, and Payment for the Preoperative Visit Prior to a Screening Colonoscopy.

INTRODUCTION

The American College of Gastroenterology (ACG) is a physician organization representing gastroenterologists and other gastrointestinal specialists. Founded in 1932, the College currently numbers more than 9,000 physicians among its membership. While the majority of these physicians are gastroenterologists, the College's membership also includes surgeons, pathologists, hepatologists and other specialists in various aspects of the overall treatment of digestive diseases and conditions. The College has chosen to focus its activities on clinical gastroenterology--the issues confronting the gastrointestinal specialist in treatment of patients. The primary activities of the College have been, and continue to be educational.

Submission of Practice Expense Surveys and Revised Resource-Based Practice Expense RVU Methodology

It is difficult to describe the College's bitter disappointment with CMS for reneging on the acceptance and utilization of the supplemental practice expense survey jointly submitted by ACG, the American Society for Gastrointestinal Endoscopy (ASGE), and the American Gastroenterological Association (AGA). CMS had signaled its acceptance of these modifications by publishing this in its proposed rule and as no preponderance of adverse comments have been cited we cannot understand the CMS action to reverse the normal administrative process. We are equally alarmed by the agency's refusal to provide the College or any of the other affected physician societies with certain **basic** but important information, such as 1) what specific miscalculation was made by CMS actuaries that caused the errant proposed relative value unit (RVU) changes for practice expense (PE) levels; 2) the gravity of the CMS miscalculation in relation to the proposed PE RVU changes; and 3) when and if the survey data, compiled at significant expense to ACG and our sister GI societies, will ever be utilized by CMS as the agency is required to do under Section 212 of the Balanced Budget and Act of 1997 (BBA). Despite correspondence and a face-to-face meeting at agency headquarters in Baltimore, CMS continues to gloss over this matter as some sort of unfortunate computer glitch that amounts to no more than a trifle to the affected parties.

As noted in the joint society (Practice Expense Supplemental Survey (PESS) Coalition) letter to CMS Administrator Mark McClellan on November 28, 2005, the Agency's decision not to utilize the already accepted PE survey data "raises substantial legal concerns and seriously impugns the agency's credibility and objectivity." The opportunity to submit supplemental PE surveys was afforded to all medical specialty societies, and CMS accepted surveys by other societies in prior years and implemented the PE changes. By failing to implement the changes based on the accepted surveys it is then **obligated** to use, CMS is failing to follow statutory guidance of Section 212 and its own subsequent administrative processes. What remains is a complete lack of confidence in the agency and its apparent violation of current regulatory procedures.

Despite protestations to the contrary, CMS had many regulatory tools at its disposal – and still many remain – to amend the problem imposed by this, as of yet undisclosed, calculation error. Whether by correction notice, extending the public comment period on the proposed rule, or making the final rule "interim" until corrections to the calculations could be made, CMS had many opportunities to make things right and preserve the faith and trust that medical societies and their physician members must have in the agency in order for the Medicare payment system and good government to prosper.

The decision for CMS to maintain the "status quo" on PE levels unjustly penalizes the physician medical societies that dedicated significant time, effort and financial and staff resources to this process. We implore CMS to immediately: 1) release the specifics of the calculation error; 2) recalculate and reissue the revised PE values; 3) provide for public comment on the revised PE values, and 4) incorporate the revised values into the 2006 physician fee schedule by March 1, 2006. Anything short of these actions reveals CMS' regulatory processes as nothing more than a sham, in addition to apparent violation of administrative law.

SGR-Initiated Physician Payment Reductions

The 4.4% decrease in physician fees for calendar year 2006 is unacceptable. It should not take an act of Congress to change this payment nightmare. Right now, organized medicine is subject to the whims of Congress, as the one-year payment "fix" is in limbo until later this month or possibly February. Even this so-called fix is merely a patch – a freeze that fails to keep pace with medical inflation or even the consumer price index. Congress gave the U.S. Department of Health and Human Services and more specifically, the Centers for Medicare and Medicaid Services (CMS), great latitude in conducting Medicare policy. The agency certainly uses broad interpretations of law and federal code when dealing with other matters – such as with the practice expense supplemental survey issue discussed above. Instead, however, it continues to punt on one of its most basic charges – adequately and fairly paying the physicians who treat its 40 million beneficiaries.

This is not to say that Congress should not have to shoulder some of the blame for the nearly annual circus that now surrounds the physician payment issue, but when the leaders of that legislative body specifically note, in writing, that they believe CMS has the authority to make the necessary changes to the sustainable growth rate formula, the onus falls upon the agency to do the job. It is high time CMS takes this responsibility seriously and presents and implements a well thought out plan to replace the SGR with a formula based on the Medicare Economic Index (MEI) in the proposed rule for the Physician Fee Schedule this summer. It has certainly had enough time to think about this problem. The agency's first order of business this year should be for the CMS Administrator to convey immediately, in writing, that the physician payment freeze included in the budget reconciliation bill should be retroactive to January 1, 2006 – regardless of when the law is enacted.

Furthermore, CMS continues to advance its own efforts to have physicians voluntarily report on specific quality measures. Advancing pay-for-performance, value-based purchasing or other quality-centered initiatives will not work so long as the SGR remains in place and physician fee cuts loom endlessly on the horizon.

Site-of-Service Policy for GI Endoscopies

The final fee schedule for 2006 leaves unaltered the disturbing site-of-service payment policy that provides a payment differential for physicians who perform gastrointestinal endoscopic procedures depending upon whether the services are provided in a Medicare certified hospital outpatient department (HOPD) or ambulatory surgery center (ASC), or in an office setting. Sadly, this policy has established such a differential without regard to which setting is most beneficial for individual patient outcomes. For example, in its proposed rule for the 2006 Fee Schedule, CMS would reimburse a physician more than double the amount ($285.01 to $115.60) for an upper GI endoscopy exam (43234) performed in the largely unregulated office setting than for the same procedure done in the state and federally regulated HOPD and ASC settings. Despite the proliferation of this CMS payment distortion since 1998, the overwhelming majority (95 percent) of gastrointestinal endoscopic procedures are still performed in the HOPD and ASC settings.

It bears repeating that the ultimate site-of-service policy adopted in 1998 did not conform to the standard HCFA/CMS established for the Clinical Practice Expert Panels (CPEPs) in 1997, and

fourteen GI procedures were included within the new site-of-service policy although office volumes for these procedures fell below the 10% threshold of total Medicare volume for the respective procedures (these remain below the 10 percent threshold). By including these specific services within the bifurcated fee schedule, CMS has been subjecting physicians who provide these services to a lower reimbursement than they would have, and should have received, had HCFA/CMS observed the 10% threshold. The gap between the two fee levels has grown wider nearly every year since 1998, and physicians providing these services in the HOPD/ASC setting now receive roughly half of the non-facility (office) reimbursement level as a result of this inconsistent HCFA/CMS policy.

We urge CMS to adopt a policy remedy which (1) shifts these GI procedures out of the site-of-service policy if they are below the 10 percent office volume threshold established in 1997; and (2) levels the playing field for eight years of under-reimbursement by setting these procedures with a single fee and total RVU at the current non-facility rate, so that prospectively all GI endoscopies will be reimbursed at the higher physician fee rate.

Payment Policies Hinder Utilization of Colorectal Cancer Screening Services

The College is hopeful that CMS took note of the actions of the U.S. Senate on November 3, 2005, when that legislative body passed, without objection, amendment 2419 to the Deficit Reduction Omnibus Reconciliation Act of 2005 (S. 1932). The amendment, offered by Senators Rick Santorum (R-PA), Joseph Lieberman (D-CT), and others, included a section (Section 6118) based on S. 1010, the Colon Cancer Screen for Life Act. This legislation would improve patient access to and utilization of Medicare's colorectal cancer screening benefit. The Screen for Life Act currently has twenty cosponsors in the Senate, in addition to Senator Santorum's chief sponsorship.

Two of the key components of the Screen for Life Act are 1) to increase payment for five specific colonoscopy services (G 0105, G 0121, CPT 45378, CPT 45380, and CPT 45385) by up to thirty percent, and 2) to pay for the preoperative visit prior to a screening colonoscopy. We want to make clear that CMS also has the ability to act on its own authority to make these desired changes to current payment policy – and should do so as soon in the rule for the CY 2007 Physician Fee Schedule.

Underpayment for Colorectal Cancer (CRC) Prevention Services

Currently, however, a significant barrier exists for greater access to and utilization of Medicare's colorectal cancer screening benefit. Reimbursement for a screening/diagnostic colonoscopy (45378, G0105 and G0121) performed in the HOPD or ASC setting has been reduced by nearly 40 percent since the Medicare CRC screening benefit was enacted in 1997, and would fall under the $200 level in 2006 under the proposed Physician Fee Schedule. Instead of payment reflecting the significance and priority Congress afforded the CRC benefit, physician reimbursement has been reduced to such a level that in about two-thirds of the states, Medicare now pays less than Medicaid for a colonoscopy (45378). Surely that was not the intent of Congress.

In 2000, the Government Accountability Office (GAO) concluded that the Medicare colon cancer screening benefit was under-utilized. **In addition, according to a report just issued by the National Cancer Institute, "screening for colorectal cancer remains low, despite its proven effectiveness," and it continues to trail screening for breast and cervical cancers by a significant margin. We maintain that under-payment remains a contributing factor in this problem. An article in the October 11, 2005 *Wall Street Journal* focused on a recently released study (published in the November 15, 2005 issue of *Cancer*) that showed that in addition to public awareness campaigns for colorectal cancer screening, "There must be ... financial incentives for physicians to screen patients," according to the study's lead author, Dr. Patricia A. Ganz of the University of California at Los Angeles's Jonsson Cancer Center.** This study seems to concur with anecdotal evidence gathered by ACG suggesting for some time that many practices are no longer accepting new Medicare patients, as Medicare colonoscopies have become a loss leader with reimbursements for these services at or below costs, and in other practices a two-tier system has developed with longer waiting periods for Medicare beneficiaries seeking screening. There is a serious policy disconnect when payment for an exam that is up to 93 percent effective in preventing the nation's number-two cancer killer has declined $100 since 1997. The payment reduction is due almost exclusively to inappropriate decisions made by HCFA/CMS.

Preoperative Visit

ACG remains hopeful that our ongoing efforts over the past two years in trying to work with CMS to adopt a policy to have Medicare pay for the preoperative clearance visit prior to a screening colonoscopy, just as it currently does for a diagnostic colonoscopy, will prove successful. This policy inconsistency and inequity has existed in the Physician Fee Schedule for six years. From a clinical standpoint, the colonoscopy procedure is the same, whether diagnostic or screening in nature. The preoperative clearance visit (conducted in advance of the procedure and not on the same day) for colonoscopy is all the more necessary when treating the Medicare population, even when not referred for a diagnostic reason. As the agency is well aware, Medicare patients – by definition – present with more comorbidities and possible complications from drug interactions related to chronic conditions than the under-65 population.

The gastroenterologist should physically examine the patient, including a discussion of medical history and drug regimens, even before ordering the pre-procedure preparation, let alone prior to sedating the patient for a colonoscopy. This should be the case regardless of whether the beneficiary's primary care physician has referred them for a screening colonoscopy. Of course, not all beneficiaries referred for a screening colonoscopy will necessarily be appropriate candidates for the procedure, and so an alternative screening measure may be recommended. JCAHO, AAAHC, and many state governments require that the patient cannot be sedated for a procedure unless he/she has been seen by the physician to determine medical history, evaluated for the appropriateness of patient's having the procedure, and preparation instructions.

We are hopeful that CMS will reconsider ACG's justification and adopt a universal policy covering the preoperative clearance visit prior to a screening colonoscopy, as well as procedures that are coded as diagnostic in nature. Finally, any coverage for the screening preoperative visit should not make payment conditional on certain diagnostic outcomes of that visit.

Conclusion

There is no secret about the benefits of practicing preventive medicine, both for improved patient outcomes and long-term cost savings to the health care system. CMS can and should take these comprehensive actions to help save lives and Medicare program dollars: 1) unify the fee schedule for gastrointestinal endoscopic procedures and pay the physician fee for all procedures at the higher office rate; 2) pay for the preoperative visit prior to a screening colonoscopy; and 3) replace the SGR with a payment system based on the Medicare Economic Index; and 4) implement the Agency's proposed practice expense adjustments based on the supplemental surveys submitted and accepted by the ACG, ASGE and AGA, as incorporated into the agency's proposed rule for the CY 2006 Medicare Physician Fee Schedule. Only then will the colon cancer screening benefit begin to approach the life-saving potential that was intended by Congress.

In closing, we would welcome the opportunity to meet with you and to respond to any questions you may have regarding our comments.

Sincerely,

Jack A. DiPalma, M.D., FACG
President

Edward L. Cattau, Jr., M.D., FACG
Chair, National Affairs Committee

ACG:mhr

50 rec'd 12/29/05

PPTA
Plasma Protein Therapeutics Association

December 28, 2005
Reference No.: HPSC05067

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1502-FC (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006)

Dear Administrator McClellan:

The Plasma Protein Therapeutics Association ("PPTA") appreciates this opportunity to comment on the final rule with comment period concerning revisions to payment policies under the 2006 physician fee schedule that was published in the Federal Register on November 21, 2005 (Final Rule). As an association deeply committed to the health and safety of the patients we serve, our comments on the rule are intended to ensure that Medicare beneficiaries have full access to the complete range of life-saving, Food and Drug Administration ("FDA") approved, plasma-based and their recombinant analog therapies ("Plasma Therapies") in the hospital outpatient setting.

PPTA is the association that represents the commercial producers of Plasma Therapies. These therapies are used by millions of people to treat a variety of diseases and serious medical conditions. PPTA members produce over 80% of the Plasma Therapies for the United States market and more than 60% worldwide. Some of the critical therapies produced by PPTA members include: blood clotting factors for people with hemophilia, intravenous immune globulins ("IVIG") used to prevent infections in people with immune deficiencies and other serious conditions, and alpha-1 proteinase inhibitors used to treat people with alpha-1-antitrypsin deficiency, also known as genetic emphysema.

With regard to the Final Rule, these comments relate solely to the agency's treatment of IVIG furnished by physicians and suppliers and represent the views of the above groups. IVIG is the only effective treatment for primary immunodeficiency disease and also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States licensed IVIG products are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals affected by diseases or

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conditions treated with IVIG depend on this life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious or potentially life threatening complications.

PPTA is very appreciative of measures taken by the Centers for Medicare and Medicaid Services (CMS) to address the ongoing IVIG access situation. While we applaud the agency's recognition of the importance of ensuring that beneficiaries have access to IVIG and a need for additional payment for preadministration services related to IVIG, we do not believe that, given the drastic payment rate reductions applicable first to physicians and suppliers in 2005 and to hospital outpatient departments in 2006, CMS has exhausted all options within its authority to preserve access to IVIG. We have seen reduced access to IVIG through physicians and suppliers because of reimbursement concerns and we believe the same will be true in the hospital outpatient department going forward. That, unfortunately, will leave no alternate site of service such that patients may no longer able to obtain IVIG through a physician's office, a supplier, or a hospital outpatient department.

We urge CMS to take immediate action to ensure that payments to physicians and suppliers that furnish IVIG to beneficiaries are sufficient to ensure access as of January 1, 2006. We believe that the agency could do so by (i) establishing a comprehensive, permanent add-on payment to the rate for IVIG that captures the true acquisition, direct and indirect handling costs associated with IVIG; (ii) establishing unique Healthcare Common Procedure Coding System ("HCPCS") codes for each brand of IVIG so that the average sales price ("ASP") for each IVIG product is based on information submitted for that product and thus reflective of each product's unique formulation; and (iii) clarifying that IVIG is a biologic response modifier for purposes of paying for administering the product. These mechanisms are discussed separately below.

A. Add-On

In our comments on the 2006 physician fee schedule proposed rule, we advocated for an add-on payment for IVIG that captures the acquisition, direct and indirect handling costs associated with the product. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of hospital acquisition costs for IVIG, it nonetheless determined that Medicare should make an additional payment of about $69 for each administration of IVIG to compensate for preadministration services related to IVIG. 70 Fed. Reg. at 70220.

PPTA appreciates the agency's recognition of these types of costs incurred in providing IVIG to beneficiaries, but believes that the additional preadministration payment is insufficient to ensure access to IVIG from physicians and suppliers, particularly in a year in which patients that migrated to hospital outpatient departments may experience less

access in that setting and have to return to physicians and suppliers. While the additional payment does reimburse for some of the costs incurred related to IVIG, other costs would remain uncompensated. As we explained in our comment letter related to the proposed rule, the Plasma Protein Therapeutics Association (PPTA) and its member companies with the input of other stakeholders in the IVIG community, commissioned the Lewin Group to develop additional information to detail the costs incur related to IVIG (see attached Lewin Group Study). These data should help us identify the costs that remain uncompensated

Moreover, we are concerned that the payment for preadministration services is labeled a temporary mechanism only for 2006. 70 Fed. Reg. at 70221. We envision that physicians and suppliers will continue to incur the costs that are compensated through this payment beyond 2006, and thus, it should be a permanent feature, augmented as suggested above to capture a fuller range of costs to furnish IVIG. Two key findings of the Lewin Group report are:

> "CMS' Final Rule CY 2006 ASPs are below the prices paid by surveyed hospitals and physicians (see slides 26 & 27) and CMS' Final Rule CY 2006 pre-service temporary add-on payment does not adequately cover pre-service costs (see slides 9, 28 & 29). Given the high level of ongoing pre-service costs, CMS could consider increasing this add-on and making it permanent. "

B. Expanded HCPCS Codes for IVIG Products

With payment for IVIG determined using the average sale price plus 6% payment methodology, we believe that CMS must take a critical step to ensure that this methodology establishes rates that are appropriate to sustain access to the various IVIG products as they are not interchangeable. Specifically, we believe that each brand name IVIG should have its own HCPCS code so that the ASP-based payment rate will be computed on its own ASP information, yielding rates that are pertinent to each brand, which should enhance access to IVIG products.

The following brands of intravenous immune globulin are now available in the United States market: Polygam® SD, Panglobulin® NF, Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, and Gammagard® Liquid. Establishing a separate HCPCS codes for each brand is appropriate because there are important clinical differences among them, such as:

- Some brands contain no sugars, which is beneficial for diabetics;
- Some brands have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some brands contain sucrose, which can create a higher risk of renal failure;
- Some brands contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and

- Some brands have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

Physicians prescribe different brands of IVIG due to these differences, yet CMS' coding and payment for these brands does not recognize such differences because there is just one code for liquid IVIG and one code for lyophilized (powder) IVIG. CMS can better assure the accuracy of the payment rates and thus promote access to all brands of IVIG by creating separate codes for each brand of IVIG. Brand specific reimbursement will serve another purpose of the agency as well – gaining an "improved understanding of the contemporary, volatile IVIG marketplace," 70 Fed. Reg. at 70220, by allowing CMS to track the individual brand name products.

According to the final rule the agency issued regarding the hospital outpatient prospective payment system, CMS considered establishing brand-specific HCPCS codes for IVIG, but did not find a "compelling" reason to override the standard practice of not establishing brand-specific codes. 70 Fed. Reg. 68516, 68648 (Nov. 10, 2005). The IVIG community respectfully believes that the Final Rule itself offers compelling reasons to override the standard practice, specifically:

- "we continue to be concerned about reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG on a consistent basis to meet their patients' needs in the current marketplace." 70 Fed. Reg. at 70219;
- "The Secretary's Advisory Committee on Blood Safety and Availability has recommended immediate steps be taken to ensure access to IVIG so that patients' needs are being met." Id.;
- "the complexity of the IVIG marketplace makes it unclear what particular systematic approaches would be most effective in addressing the many individual circumstances that have been shared with us while not exacerbating what appears to be a temporary disruption in the marketplace." Id.;
- "Historically, numerous factors, including decreased manufacturer capacity, increased usage, more sophisticated processing steps, and low demand for byproducts from IVIG fractionation have affected the supply of IVIG." Id.;
- An additional payment for preadministration services is needed to "ensure that Medicare beneficiaries depending upon IVIG experience no adverse health consequences from the market instability for IVIG products." 70 Fed. Reg. at 70221; and
- "Based on the potential access concerns, the growing demand for IVIG, and the unique features of IVIG detailed above, as we seek to gain improved understanding of the contemporary volatile marketplace, we will employ a two-pronged approach during CY 2006 to help ensure the availability of IVIG to physicians and hospital outpatient departments." 70 Fed. Reg. at 70220.

We submit that the totality of these statements, in particular the decision to take a two-pronged approach to ensure continued access to IVIG across treatment settings, makes clear that there are compelling reasons to override the standard practice of not establishing brand-specific HCPCS codes. Accordingly, we urge CMS to issue brand-specific codes for IVIG products for use effective January 1, 2006.

C. IVIG Is a Biologic Response Modifier

CMS has incorporated the new Current Procedural Terminology ("CPT") codes to bill for drug administration services in 2006, as it indicated was likely in the proposed rule. Under these new codes, chemotherapy administration codes apply to "substances such as monoclonal antibody agents, and other biologic response modifiers."1 As a result, when a physician administers a biologic response modifier, even though it may not be "chemotherapy," it is appropriate to bill 96413 for the administration service. The IVIG community urges CMS to clarify, in forthcoming instructions on billing for drug administration services or otherwise, that IVIG is a biologic response modifier and that physicians should bill for administering it under 96413 effective for services furnished on or after January 1, 2006.

Based on the above-quoted language in CPT 2006, any product that is a "biologic response modifier" should be billed under a chemotherapy administration code and IVIG is such a product. According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to "immunotherapy," which is categorized as "Treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."2 IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Accordingly, we urge CMS to provide written guidance indicating that IVIG is a biologic response modifier for purposes of billing for administering the product.

CONCLUSION

PPTA appreciates the opportunity to comment on the Final Rule. We recognize and greatly appreciate CMS' effort and commitment to ensure patient access to IVIG and believe that further measures are needed in order to alleviate this ongoing situation. We are deeply concerned about the impact the Final Rule could have on beneficiary access to a life saving therapy, especially since there are limited other options as a site of care for patients dependent upon IVIG. In this comment letter, we offer three mechanisms to ensure that such beneficiaries will have continued access to IVIG through physicians and suppliers – a permanent and comprehensive add-on payment, establishment of

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1 CPT 2006 Current Procedural Terminology Professional Edition, at p. 400.

2 See http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy .

brand-specific HCPCS codes, and recognition of IVIG as a biologic response modifier for purposes of drug administration billing. As explained above, there are ample reasons for CMS to take all three actions effective January 1, 2006.

We look forward to continuing to work with CMS to ensure continued access to IVIG furnished by physicians and suppliers. Please contact me at 202-789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter. We would welcome the opportunity to meet to further discuss the Lewin Group data and findings.

Respectfully submitted,

Julie Birkofer

Julie A. Birkofer
Executive Director, North America

Attachment: Lewin Group Study - Assessing the Cost of IVIG Infusion Services in Physician Offices & Hospital Pharmacy Departments

Assessing the Cost of IVIG Infusion Services in Physician Offices & Hospital Pharmacy Departments

Prepared for:

Plasma Protein Therapeutics Association

December 27, 2005

Table of Contents

Executive Summary

- Survey data were collected from 76 physician offices and 30 hospital pharmacy departments to compare CMS payments to current physician office and physician time costs.
- Physicians and hospitals reported that reduced physician Medicare payments beginning in 2004 resulted in a migration of patients from physician offices to the outpatient hospital setting.
- It appears that CMS' attempt to correct for perceived overpayment for IVIG product in 2004 "overcorrected," and physicians are currently being paid less than their total costs incurred for the provisions of IVIG infusions for both product and services. Hospitals will also be paid less than their costs by CMS beginning CY 2006 (see slide 25).
- Underpayments for services understate losses for providers who perform even a small number of infusions each month (see slides 30 & 31).

Executive Summary (continued)

- CMS' Final Rule CY 2006 ASPs are below the prices paid by surveyed hospitals and physicians (see slides 26 & 27).
  - The average price surveyed physicians reported paying is about 8% above CMS' ASP for both lyophilized and liquid product ($450 - $500 per infusion) [1]
  - The average price surveyed hospitals reported paying is about 9% above CMS' ASP for both lyophilized and liquid product (and $150 - $250 per infusion) [1,2]
- CMS' Final Rule CY 2006 pre-service temporary add-on payment does not adequately cover pre-service costs (see slides 9, 28 & 29). Given the high level of ongoing pre-service costs, CMS could consider increasing this add-on and making it permanent.
  - Almost half (45%) of physician office pre-service costs are not covered by the $69 temporary add-on payment. Only about 10% of pre-service costs are attributed to inventory procurement and management costs ($8.76) [3]
  - The CMS $75 hospital outpatient add-on payment adequately covers inventory management and procurement costs for hospital pharmacies, however, it is unlikely that it covers all other pre-service costs [3]

[1] Based on 50 grams of lyophilized or liquid IVIG
[2] Hospital average reported price paid per infusion is based on contract prices only; off contract prices are generally higher.
[3] Additional pre-service tasks include patient contacts and insurance pre-certification.

Executive Summary (continued)

- **Physician Offices**
  - CMS payment rates do not cover total physician office costs for either lyophilized or liquid IVIG infusions (see slides 30 & 31).
  - Based on the number of infusions performed per month, physician office total monthly costs exceeded CMS payments.
  - Unmet costs are outlined below:

	6 infusions	10 infusions (median)	25 infusions (average)
Lyophilized	-$2,339.16	-$3,898.60	-$9,746.51
Liquid	-$1,868.76	-$3,114.60	-$7,786.51

Some corrections to the CMS Final Rule CY 2006 ASP and proposed pre-service add-on payments are necessary to ensure that physicians and hospitals will continue to provide this life-sustaining service to Medicare beneficiaries.

Providing IVIG Infusion Services

- IVIG infusion services are currently provided by an increasing number of hospitals and physician specialists.
- Treatment varies in amount of product provided over time, as well as speed, concentration and frequency of infusions.
- There is complexity and special training required with administration of any biological product.
- Physicians, hospital pharmacists and staff expend extra hours obtaining appropriate IVIG products.
- When lack of availability of specific IVIG products require that a patient switch products, additional clinical time is needed for evaluation and monitoring.
- Patients' clinical indications, medical conditions and past reactions to various products determine recommendations for specific products.
- As a result of the above factors, IVIG pre-infusion services to include documentation are more resource-intensive than other infusions.

Estimated CMS 2006 Physician Payments for IVIG Infusions: Case Examples

			Case 1 3 hours @ 32 g	Case 2 5 hours @ 50 g	Case 3 6 hours @ 85 g
CMS ASP Alone (Final Rule CY 2006)	Lyoph. Liquid	$40.16 $53.11			
With 6%	Lyophilized	$42.57	$1,362.24	$2,128.50	$3,618.45
	Liquid	$56.30	$1,801.60	$2,815.00	$4,785.50
GO332	Temp add on	$69.00	$69.00	$69.00	$69.00
36000	IV placement	$27.13	$27.13	$27.13	$27.13
90765	Infusion, 1st hr	$73.80	$73.80	$73.80	$73.80
90766	Subsequent hours	$24.60	$49.20	$98.40	$123.00
	Subtotal		**$219.13**	**$268.33**	**$292.93**
Estimated Total Lyophilized CMS Payment			$1,581.37	$2,396.83	$3,911.38
Reported Lyophilized Cost			$1,871.43	$2,776.29	$4,535.74
Estimated Total Liquid CMS Payment			$2,020.73	$3,083.33	$5,078.43
Reported Liquid Cost			$2,277.67	$3,405.19	$5,597.59

Components of IVIG Infusion Costs

- Pre-Service
  - Check inventory*
  - Locate & procure product*
  - Place order*
  - Shelving and storing*
  - Pre-certification/verification of insurance
  - Telephone patient assessment /confirm appointment
  - Prepare and/or reconstitute IVIG product*
  - History
  - Vital check
  - Physical exam
- Clinical Administration
  - IV start
  - Pre-medication administration
  - Physician coordination and monitoring
  - Adverse events intervention
  - Discontinue IVIG infusion
- Post-Service
  - Immediate post-infusion assessment
  - Post-infusion assessment by telephone (w/in 24 hours)

* Components of hospital costs reported in study (pharmacy departments only)

Total Physician Office CMS Reimbursement and Survey Costs

Practice Expense & Physician Work Combined

	CMS Payment 2006			Survey Costs of Service	
	Case 1 3hr @ 32g	Case 2 5hr @ 50g	Case 3 6hr @ 85g	Lyophilized	Liquid
Pre-Service	$69.00	$69.00	$69.00	$134.30*	$123.90*
Clinical Administration	$174.73	$199.33	$223.93	$121.28	$121.28
Post-Service	$0.00	$0.00	$0.00	$17.61	$17.61
Total	$243.73	$268.33	$292.93	$273.19	$262.79

* The CMS pre-service payment was developed to cover costs in CY 2006 due to "temporary market instability". CMS has indicated it will likely not be needed later. Survey data indicate the bulk of pre-service costs are not market sensitive. Procurement and inventory management costs represent less than 12% of all pre-service costs. The majority of pre-service costs are on-going, regardless of market conditions.

Supply costs are included in the Clinical Administration category and are reported as $21.16 for both products, although the costs are estimated to vary by less than $3.

To date, respondents have not indicated the cost associated with owning and operating IV pumps. Neither this cost, nor the cost of pump supplies are included in the above numbers, although 60% of respondents reported using pumps at least some of the time.

NOTES: A breakdown of costs (Practice Expense and Physician Work) is presented in the supporting documentation. CMS has indicated physicians may bill E&M codes, Levels 2-5, under certain circumstances, which do not reflect the typical IVIG infusion case. The above CMS rates include malpractice payments; the survey rates include malpractice payments assuming a 5 hour infusion. While CMS payment rates are based on infusion time, survey data reflect average infusion costs overall.

Comparing CMS Calculated Reimbursement Per Gram to Acquisition Cost Prices

	CMS Final Rule CY 2006 ASP	Acquisition Costs*		Distributor/Manufacturer Price	
		Contract	Total (Contract and Off Contract)	Contract	Total (Contract and Off Contract)
PHYSICANS					
Lyophilized					
Average	$40.16	$44.57	$50.27	$43.50	$47.47
Liquid					
Average	$53.11	$58.36	$62.64	$54.33	$56.86
HOSPITALS					
Lyophilized					
Average	$40.16	$45.54	**	$42.79	$46.98
Liquid					
Average	$53.11	$56.09	**	$56.59	$58.47

- Data reflect reported distributor and manufacturer prices for "direct to physician" or "direct to hospital" sales. Reported distributor prices are estimated to represent over 55% of the physician market, while manufacturer prices include all reported manufacturer sales YTD through Q3 of 2005. All distributor ASPs reflect YTD totals as reported by distributors through November 2005.

*As reported by survey respondents.

**Hospitals reported paying between $45 and $156 per gram off-contract with widely varying amounts and products, depending on patient need and brand availability.

Study Results - Hospital Pharmacy Departments

- 30 hospital pharmacists were interviewed representing 37 facilities providing outpatient IVIG services. Respondent hospitals include a wide range of bed sizes throughout the U.S.
- Pharmacy preparation costs analyzed include checking inventory, locating & procuring product, placing order, shelving and storing, preparing and/or reconstituting IVIG product. These costs represent a small subset of costs included in the physician office analysis.
- Surveyed pharmacy departments ordered between 100 and >7,000 grams of IVIG a month, and performed between 2 and >100 infusions a month.

Study Results – Hospital Pharmacy Departments (continued)

- Some hospitals surveyed chose to stop seeing new patients rather than purchase higher priced, off-contract IVIG.
- Half reported purchasing IVIG off-contract in the past year; nearly one-quarter of those reported making regular purchases off contract.
- Off-contract prices can be more than double the contracted ASPs, depending on the distributor.

Reported Hospital Pharmacy Handling Costs

50 grams Per Dose (1 Infusion)

Lyophilized

	Cost per Gram	Total Cost per Dose	% of CMS Final Rule CY 2006 ASP
Low	$0.21	$10.50	0.5%
Median	$0.90	$45.00	2.2%
High	$3.98	$199.00	9.9%

Liquid

	Cost per Gram	Total Cost per Dose	% of CMS Final Rule CY 2006 ASP
Low	$0.21	$10.50	0.4%
Median	$0.76	$38.00	1.4%
High	$3.42	$171.00	6.4%

Costs of pre-infusion services performed outside of hospital pharmacy (such as pre-certification, scheduling appointments, and other patient contact) were not included in the hospital pilot study. No clinical administration or post-infusion services were examined in the hospital pilot study.

Challenges in Obtaining & Administering IVIG

- Physicians and hospitals reported that reduced physician Medicare payments beginning 2004 resulted in a migration of patients from physician offices to outpatient hospital setting.
- Physicians referring Medicare patients to hospitals have found that hospitals are sometimes unable to procure the same products, thus, requiring more time for clinical monitoring/addressing adverse events.
- Access to certain IVIG products can vary by month, sometimes increasing clinical administration time and patient outcomes.

Challenges in Obtaining & Administering IVIG (continued)

- Product type, rate of infusion, product concentration, patient tolerance, brand availability and physician practice styles result in significant variation in costs.
- Many tasks associated with preparing for IVIG administration are performed by clinicians, whose higher costs are often not recognized or paid for by payers, including Medicare.
- Changing patient needs and the normal fluctuations in volume cannot always be predicted. This unpredictability in need combined with the migration of patients from physician offices to the hospital outpatient setting have resulted in some providers having to purchase additional product off-contract and pay much higher prices.

Acknowledgements

- Support from various Stakeholders including:
  - The Immune Deficiency Foundation (IDF)
  - The Neuropathy Association
  - Participating Hospital Pharmacy Directors and Physician Offices

The Lewin Group

- The Lewin Group is a premier national health and human services consulting firm with 35 years of experience delivering objective analyses and strategic counsel to prominent public agencies, non-profit organizations, and private companies across U.S.
- Lewin has worked in all aspects of healthcare provider payment, and conducted Congressionally mandated studies for Centers for Medicare and Medicaid Services (CMS) as well as the Medicare Payment Advisory Commission (MedPAC) on pharmacy-related issues, and has recently completed a project for CMS to study the standards of practice for long term care pharmacies.
- Lewin helps clients to:
  - Improve policy and expand knowledge about health systems
  - Enact, implement, and evaluate programs to enhance delivery and financing
  - Adapt to shifts in health care practice, technology and regulation
  - Optimize performance, quality, coverage and health outcomes
  - Create strategies for institutions, communities, governments and consumers to make health care services systems more effective

Supporting Documentation:

Assessing the Cost of IVIG Infusion Services in Physician Offices and Hospital Pharmacy Departments

Table of Contents: Supporting Documentation

- Study Purpose
- Study Methods
- Study Results
  - Physician Offices
  - Hospital Pharmacy Departments
- Study Limitations

Study Purpose

- To identify the costs of providing IVIG infusion in physician offices and IVIG preparation costs in hospital pharmacy departments
- To approximate the total and component costs, on average, for providing IVIG infusions in physician offices and preparing IVIG in hospital pharmacies
- To compare CMS IVIG physician office infusion payments to cost incurred while providing IVIG infusion therapy
- To compare physician time (valued in terms of physician salaries*) to physician payments under the RBRVS
- To determine the impact of CMS physician payment policies on physicians' willingness to provide IVIG infusions in physician's offices

* Physician salaries were obtained from the 2004 Bureau of Labor Statistics Occupational Employment Survey. Benefit costs were obtained from BLS Employer Costs for Employee Compensation: June 2005

Study Methods

- Review past and current Medicare IVIG reimbursement
- Develop understanding of IVIG market as it affects providers
- Collect distributor and manufacturer pricing
- Physician
  - CMS IVIG payments were examined over time (through the Federal Register 2003-2006) by Practice Expense, Physician work and Total payments.
  - Design survey instrument with Technical Advisory Panel to collect total and component cost information of IVIG in physician offices
  - Distribute survey to over 1,000 physician offices via multiple channels
    - Immune Deficiency Foundation (IDF) mailing list
    - FFF Enterprises distribution system
    - The Neuropathy Association Advisory Committee members
    - IVIG Summit Group Members' recommendations
- Hospital
  - Conduct telephone survey of hospital pharmacy departments
  - Collect cost information for:
    - Handling and procurement
    - Cost of goods
- Conduct data analyses and policy interpretation

Study Sample - Physician Offices

- 76 physician sites, including several large multi-specialty groups
- 1 large multi-specialty group of over 80 sites (counted as a single site in above total)
- Individual practices represented: Allergy and Immunology, Hematology / Oncology, Infectious Disease, Neurology, Rheumatology, and Multi-Specialty groups
- Survey responses in terms of diagnoses are reflective of the overall market place
- Number of IVIG infusions performed per month range from 1 to 150 per site, with a median of 10, an average of 25
- Overhead expenses are included in all survey calculations at 36.5%

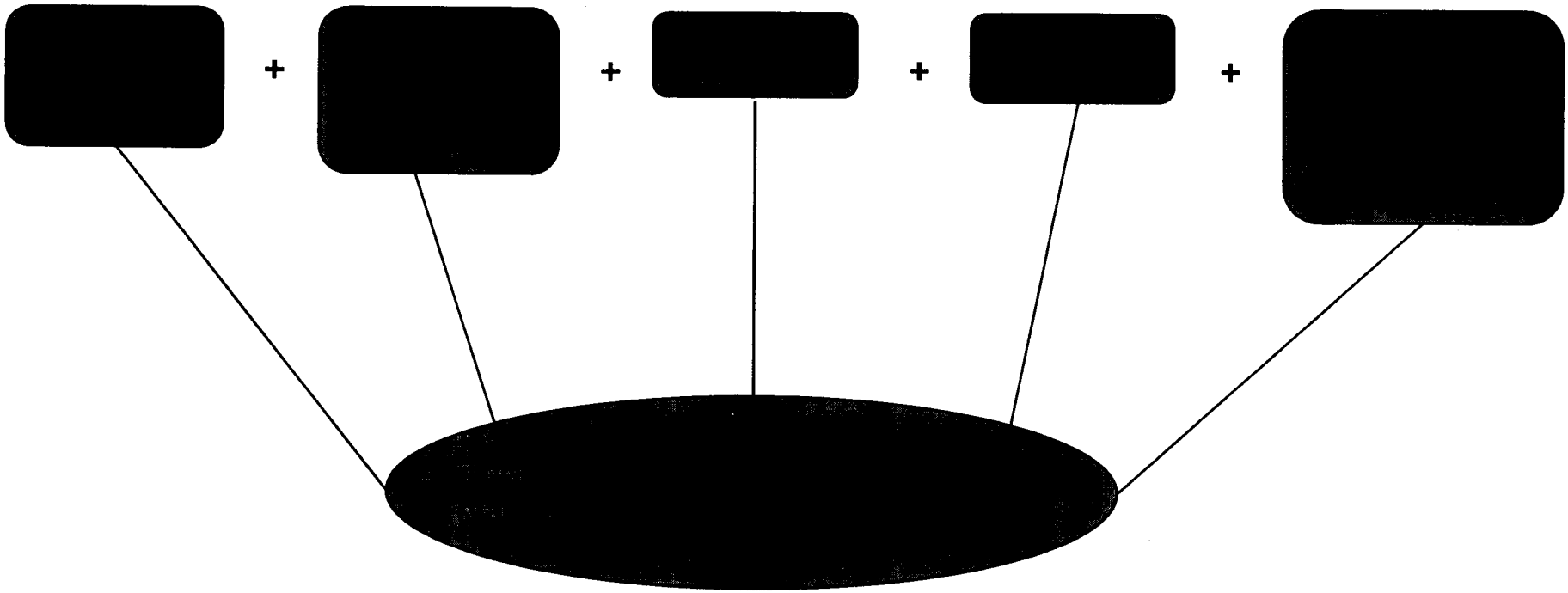
Study Sample - Hospital Pharmacy Departments

- 200+ calls yielding 30 hospital interviews
- Interviews represent 37 hospitals' experience
- Coverage: rural, urban and suburban, non-teaching and teaching, across all regions of United States
- Bed Size: 100 to 800
- IVIG Grams/Month: 100 to 7,000+
- Infusions/Month: 2 to 100+ (outpatient)

Distribution of Physician Survey Diagnoses

Primary Reported Diagnoses	Survey Percent Reported
PID/CVID/Other Hypogammaglobunemia/X-linked agammaglobulenemia (XLA)	52.3%
CIDP /peripheral neuropathy/other neurological	13.5%
Idiopathic Thrombocytopenic Purpura (ITP)	13.5%
Chronic Lymphocytic Leukemia (CLL)	4.5%
Dermatomyositis/Polymyositis	4.5%
Multiple Sclerosis	2.6%
Myasthenia Gravis	2.6%
Guillan Barre Syndrome / Post Acute Infective polyneuritis	1.9%
Auto Immune Disease - not specified	1.3%
Multiple Myeloma	1.3%
Lupus	0.6%
Post Bone Marrow Transplant	0.6%
Pemphigus	0.6%

CMS Payments for IVIG Infusion – Physician Offices



NOTE: This analysis does not include potential Evaluation & Management (E&M) code or IV Pump Supplies, neither of which are always billed by physicians offices for IVIG infusions.

IVIG CMS Payment Rates – 2006

Cost of Goods [CMS Final Rule (FR) CY 2006]		
J1566 - IVIG, lyophilized	$ 40.16/g	
J1567 - IVIG, liquid	$ 53.11/g	
PLUS 6%	$ 42.57/g	
	$ 56.30/g	
Pre-Administration (Practice expense RVU*)		
G0332 (temporary 2006 only)	$ 69.00/infusion (physician office)	
	$ 75.00/infusion (hospital outpatient)	
Clinical Administration		
IV Placement (HCPCS 36000)	$ 27.13	
90765, Infusion, initial hour	$ 73.80	/1st hr
90766, Infusion, each add'l hr	$ 24.60	/subsequent hours
Pump Supplies (only when using IV pump)		varied
E&M Codes only paid if ≥ 20 min. MD time		occasional/varied
Post-Administration	$ 00.00	

*RVU= relative value unit

Study Results

- Physician Offices
  - Trends in CMS Payment for IVIG Infusions: 2003 - 2006
  - Comparing ASPs:
    - CMS
    - Manufacturers and distributors
    - Study responses
  - Comparing CMS and study infusion payments
- Hospital Pharmacy Departments

Trends in CMS Physician Payments for IVIG Infusions: 2003 - 2006

Case 2: 50 grams of IVIG; 5 hour infusion

	CMS CY 2003	CMS CY 2004	CMS Q2 2005	CMS FR CY 2006
Conversion Factor	$36.79	$37.34	$37.98	$36.18
Cost of Goods: ASP + 6%*				
Lyophilized	$3,900.00	$2,600.00	$2,102.00	$2,128.50
Liquid	$3,900.00	$2,600.00	$2,796.00	$2,815.00
Clinical Administration				
GO332 2006 Temp add on	$0.00	$0.00	$0.00	$69.00
36000 IV Placement	$30.80	$29.12	$29.12	$27.13
90765 1st hr	$35.84	$116.56	$80.95	$73.80
90766 Subsequent hrs	$142.56	$132.60	$109.36	$98.40
Estimated lyophilized CMS	$4,109.20	$2,878.28	$2,321.43	$2,396.83
Estimated liquid CMS Payment	$4,109.20	$2,878.28	$3,015.43	$3,083.33

*In 2003, 2004 and Q1 2005, a single code was used for lyophilized and liquid forms of IVIG

Comparing CMS Calculated Reimbursement Per Gram to Acquisition Cost Prices

Lyophilized

	CMS FR CY 2006 ASP	Physician Acquisition Costs*		Distributor/Manufacturer Price	
		Contract	Total (Contract and Off Contract)	Contract	Total (Contract and Off Contract)
Low		$37.65	$38.00	$39.16	$31.64
Weighted Avg		$43.47	$45.71	$41.95	$49.78
Median		$43.99	$44.00	$43.56	$45.43
Average	$40.16	$44.57	$50.27	$43.50	$47.47
High		$70.00	$125.00	$49.72	$68.19

- Data reflect reported distributor and manufacturer prices for "direct to physician" or "direct to hospital" sales. Reported distributor prices are estimated to represent over 55% of the physician market, while manufacturer prices include all reported manufacturer sales YTD through Q3 of 2005. All distributor ASPs reflect YTD totals as reported by distributors through November 2005.
- All distributor and distributor/manufacturer "weighted average" figures have been weighted by the estimated total number of grams sold by distributors to physicians for YTD 2005 as reported. Low and high values are respectively the lowest and highest value in the distribution. The average is the sum of all the prices divided by the number of prices. The median is middle value in a distribution, where an equal number of values fall above and below it.
- Figure for Lyophilized Low for Total Distributor/Manufacturer represents an off-contract price. The next lowest off-contract price for this category is $44.89.

* As reported by survey respondents

Comparing CMS Calculated Reimbursement Per Gram to Acquisition Cost Prices

Liquid

	CMS FR CY 2006 ASP	Physician Acquisition Costs*		Distributor/Manufacturer Price	
		Contract	Total (Contract and Off Contract)	Contract	Total (Contract and Off Contract)
Low		$52.00	$52.00	$48.33	$48.33
Weighted Avg		$56.96	$60.60	$54.63	$56.62
Median		$56.95	$57.90	$54.83	$56.50
Average	$53.11	$58.36	$62.64	$54.33	$56.86
High		$79.50	$150.00	$65.00	$69.34

- Data reflect reported distributor and manufacturer prices for "direct to physician" or "direct to hospital" sales. Reported distributor prices are estimated to represent over 55% of the physician market, while manufacturer prices include all reported manufacturer sales YTD through Q3 of 2005. All distributor ASPs reflect YTD totals as reported by distributors through November 2005.
- All distributor and distributor/manufacturer "weighted average" figures have been weighted by the estimated total number of grams sold by distributors to physicians for YTD 2005 as reported. Low and high values are respectively the lowest and highest value in the distribution. The average is the sum of all the prices divided by the number of prices. The median is middle value in a distribution, where an equal number of values fall above and below it.
- Figure for Lyophilized Low for Total Distributor/Manufacturer represents an off-contract price. The next lowest off-contract price for this category is $44.89.

* As reported by survey respondents

IVIG Physician Reimbursement/Costs: Practice Expense (excluding physician work)

	CMS Payment 2006			Survey Costs of Service	
	Case 1 3hr @ 32g	Case 2 5hr @ 50g	Case 3 6hr @ 85g	Lyophilized	Liquid
Pre-Service	$69.00	$69.00	$69.00	$90.51	$78.44
Clinical Administration	$155.19	$173.28	$191.37	$95.28	$95.28
Post-Service	$0.00	$0.00	$0.00	$13.47	$13.47
Total	$224.19	$242.28	$260.37	$199.26	$187.19

* The CMS pre-service payment was developed to cover costs in CY 2006 due to "temporary market instability". CMS has indicated it will likely not be needed later. Survey data indicate the bulk of pre-service costs are not market sensitive. Procurement and inventory management costs represent less than 12% of all pre-service costs. The majority of pre-service costs are on-going, regardless of market conditions.

Supply costs are included in the Clinical Administration category and are reported as $21.16 for both products, although the costs are estimated to vary by less than $3.

To date, respondents have not indicated the cost associated with owning and operating IV pumps. Neither this cost, nor the cost of pump supplies are included in the above numbers, although 60% of respondents reported using pumps at least some of the time.

NOTES: CMS has indicated physicians may bill E&M codes, Levels 2-5, under certain circumstances, which do not reflect the typical IVIG infusion case. The above CMS rates include malpractice payments; the survey rates include malpractice payments assuming a 5 hour infusion. While CMS payment rates are based on infusion time, survey data reflect average infusion costs overall.

IVIG Physician Reimbursement/Costs: Physician Work

	CMS Payment 2006			Survey Costs of Service	
	Case 1 3hr @ 32g	Case 2 5hr @ 50g	Case 3 6hr @ 85g	Lyophilized	Liquid
Pre-Service	$0.00	$0.00	$0.00	$43.79	$45.46
Clinical Administration	$19.54	$26.05	$32.56	$26.00	$26.00
Post-Service	$0.00	$0.00	$0.00	$4.14	$4.14
Total	$19.54	$26.05	$32.56	$73.93	$75.60

NOTE: CMS has indicated physicians may begin billing E&M codes, Levels 2-5, for certain IVIG infusion-related services. This new payment in 2006 would not reflect the above reported costs involving physician work for average IVIG infusion cases. These include tasks such as quick physical exams, patient histories, etc.

While CMS payment rates are based on infusion time, survey data reflect average infusion costs overall.

Total Infusion Cost per Month: CMS vs. Physician Office Data (Lyophilized)

50 grams of IVIG; 5 hours infusion; Lyophilized

	Cost Per Infusion		Cost per Month					
			CMS 2006 (percentile) *			Survey Costs of Service (percentile) *		
	CMS Final Rule CY 2006	Survey	6 infusions	10 infusions (median)	25 infusions (average)	6 infusions	10 infusions (median)	25 infusions (average)
Cost of Goods	$2,128.50	$2,513.50	$12,771.00	$21,285.00	$53,212.50	$15,081.00	$25,135.00	$62,837.50
Pre-Service	$69.00	$134.30	$414.00	$690.00	$1,725.00	$805.80	$1,343.00	$3,357.50
Clinical Administration	$199.33	$121.28	$1,195.98	$1,993.30	$4,983.25	$727.67	$1,212.78	$3,031.96
Post-Service	$0.00	$17.61	$0.00	$0.00	$0.00	$105.67	$176.12	$440.30
Total	$2,396.83	$2,786.69	$14,380.98	$23,968.30	$59,920.75	$16,720.14	$27,866.90	$69,667.26

Physician Offices total non-reimbursed **monthly costs** based on the number of infusions:

6 infusions	10 infusions (median)	25 infusions (average)
-$2,339.16	-$3,898.60	-$9,746.51

Total Infusion Cost per Month: CMS vs. Physician Office Data (Liquid)

50 grams of IVIG; 5 hours infusion; Liquid

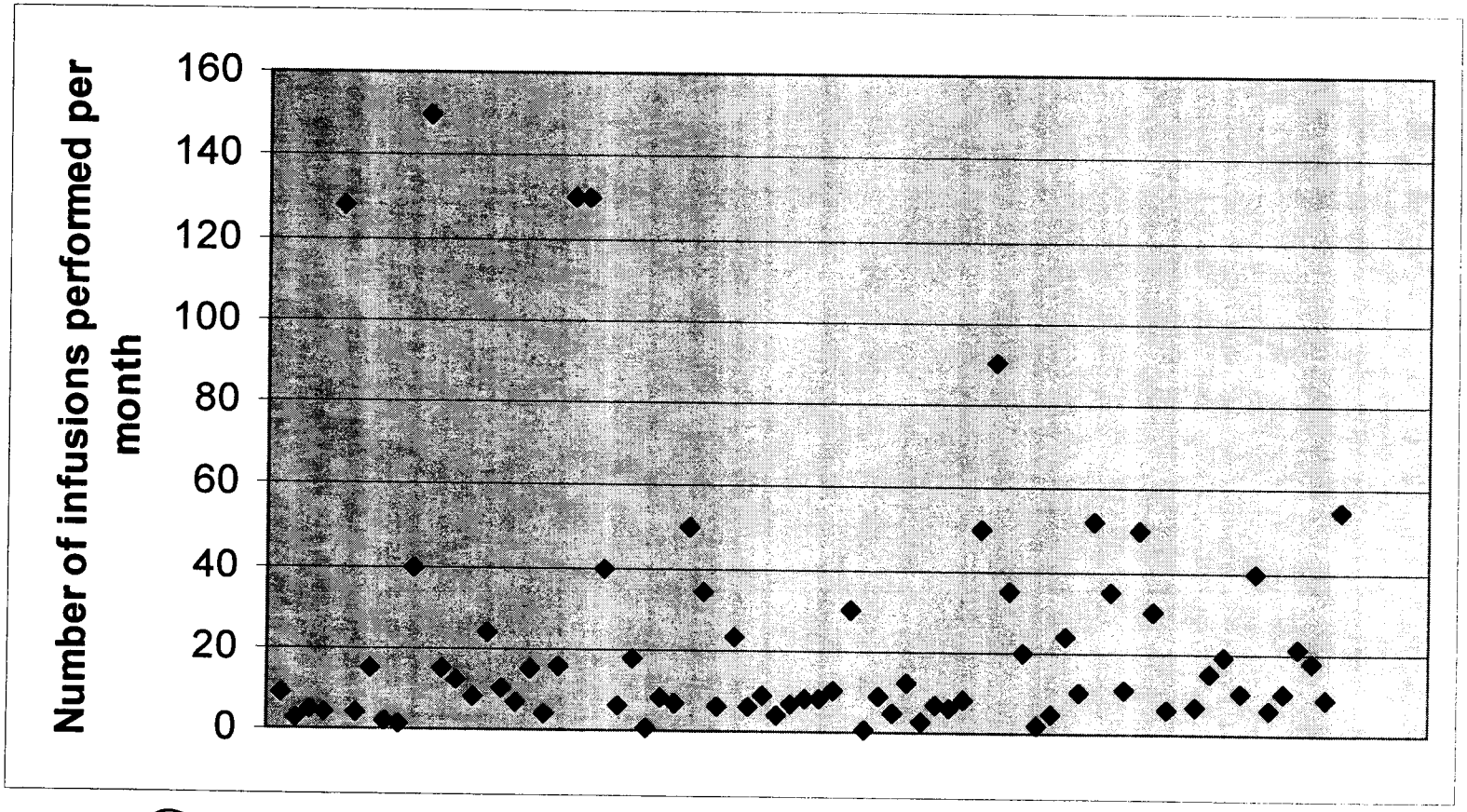
	Cost Per Infusion		Cost per Month					
			CMS 2006 (percentile) *			Survey Costs of Service (percentile) *		
	CMS Final Rule CY 2006	Survey	6 infusions	10 infusions (median)	25 infusions (average)	6 infusions	10 infusions (median)	25 infusions (average)
Cost of Goods	$2,815.00	$3,132.00	$16,890.00	$28,150.00	$70,375.00	$18,792.00	$31,320.00	$78,300.00
Pre-Service	$69.00	$123.90	$414.00	$690.00	$1,725.00	$743.40	$1,239.00	$3,097.50
Clinical Administration	$199.33	$121.28	$1,195.98	$1,993.30	$4,983.25	$727.67	$1,212.78	$3,031.96
Post-Service	$0.00	$17.61	$0.00	$0.00	$0.00	$105.67	$176.12	$440.30
Total	$3,083.33	$3,394.79	$18,499.98	$30,833.30	$77,083.25	$20,368.74	$33,947.90	$84,869.76

Physician Offices total non-reimbursed **monthly costs** based on the number of infusions:

6 infusions	10 infusions (median)	25 infusions (average)
-$1,868.76	-$3,114.60	-$7,786.51

Distribution of Physician Office IVIG Infusions per Month

The typical physician office performs between 6 and 24 IVIG infusions per month



Study Limitations

- Physician
  - Respondents were primarily immunologists and hematologists/oncologists
  - Hematologists/oncologists reported significantly lower costs than other specialties; average practice costs across specialties may be under-reported
  - This study did not focus on determining overhead costs by specialty
- Hospital
  - Smaller sample size than the physician survey
  - Pilot study conducted under tight timeframe
  - No systematic reporting of off-contract prices paid

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rec'd 12/29/0

AMERICAN
PSYCHOLOGICAL
ASSOCIATION
PRACTICE ORGANIZATION

December 23, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave. SW
Washington, DC 20201

Re: CMS-1502-FC: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006

Dear Dr. McClellan:

The American Psychological Association (APA) is pleased to offer comments on the proposed Medicare Fee Schedule for 2006. APA is the professional organization representing more than 150,000 members and associates engaged in the practice, research and teaching of psychology.

APA commends the Centers for Medicare and Medicaid Services (CMS) for assigning professional work relative values for the revised CPT codes for psychological and neuropsychological testing. We believe that adopting the new set of codes for psychological and neuropsychological testing is a very positive step. By recognizing the professional work of the psychologist and the limited yet very important use of technicians in testing environments, Medicare's payment levels better reflect the true costs of providing these services. This shift in reimbursement policy will benefit beneficiaries by increasing access to testing services.

APA thanks CMS for its many years of working with us, the CPT Editorial Panel and the RVS Update Committee to revise these codes. We look forward to continued work with CMS staff on other policy initiatives important to the practice of psychology.

Sincerely,

Russ Newman, PhD, JD
Executive Director

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52
rec'd 12/29/05

December 28, 2005

BY HAND DELIVERY

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1502-FC (Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006)

Dear Administrator McClellan:

On behalf of a diverse group of organizations committed to assuring Medicare beneficiary access to lifesaving intravenous immune globulin (IVIG) therapies, we appreciate this opportunity to comment on the final rule with comment period concerning revisions to payment policies under the 2006 physician fee schedule that was published in the Federal Register on November 21, 2005 (Final Rule). 70 Fed. Reg. 70116. As a group of patient and provider organizations and industry participants, we are deeply committed to the health and safety of the Medicare beneficiaries who rely upon access to IVIG.

Throughout the fall, a group representing various sectors of the IVIG community has met in Washington, D.C. to discuss strategies for alleviating IVIG reimbursement problems experienced by Part B physicians and suppliers since the change in reimbursement methodology on January 1, 2005. This group includes representatives from patient advocacy organizations, including the Immune Deficiency Foundation (IDF), the Jeffrey Modell Foundation (JMF) and the Neuropathy Association (TNA); the medical community, including the American Academy of Allergy, Asthma and Immunology (AAAAI); health care group purchasing organizations, including Amerinet; distributors of IVIG represented by ASD Healthcare, Cardinal Health, FFF Enterprises, and the Specialty Pharma Distributors Association; and manufacturers of IVIG represented by the Plasma Protein Therapeutics Association and its member companies. The group represents over 80% of patients using IVIG, the manufacturers of over 80% of the plasma therapies for the United States (and more than 60% worldwide), the purchasers for more than 3,800 of our nation's hospitals, and the distributors of in excess of 80% of IVIG in the United States.

With regard to the Final Rule, these comments relate solely to the agency's treatment of IVIG furnished by physicians and suppliers and represent the views of the above groups. IVIG is the only effective treatment for primary immunodeficiency disease and

also has been proven clinically beneficial in the treatment of secondary immune deficiency diseases. In addition, individual United States licensed IVIG products are labeled for the treatment of: a) Kawasaki's disease; b) chronic lymphocytic leukemia or HIV infection during childhood to prevent bacterial infections; c) bone marrow transplantation to prevent graft versus host disease and bacterial infections in adults; and d) idiopathic thrombocytopenic purpura. Many individuals affected by diseases or conditions treated with IVIG depend on this life saving therapy for the rest of their lives. Each individual needs to have maximum access to the specific formulation which best meets their unique needs and does not pose serious or potentially life threatening complications.

The IVIG community is very appreciative of measures taken by the Centers for Medicare and Medicaid Services (CMS) to address the ongoing IVIG access situation. While we applaud the agency's recognition of the importance of ensuring that beneficiaries have access to IVIG and a need for additional payment for preadministration services related to IVIG, we do not believe that, given the drastic payment rate reductions applicable first to physicians and suppliers in 2005 and to hospital outpatient departments in 2006, CMS has exhausted all options within its authority to preserve access to IVIG. We have seen reduced access to IVIG through physicians and suppliers because of reimbursement concerns and we believe the same will be true in the hospital outpatient department going forward. That, unfortunately, will leave no alternate site of service such that patients may no longer able to obtain IVIG through a physician's office, a supplier, or a hospital outpatient department.

We urge CMS to take immediate action to ensure that payments to physicians and suppliers that furnish IVIG to beneficiaries are sufficient to ensure access as of January 1, 2006. We believe that the agency could do so by (i) establishing a comprehensive, permanent add-on payment to the rate for IVIG that captures the true acquisition, direct and indirect handling costs associated with IVIG; (ii) establishing unique Healthcare Common Procedure Coding System ("HCPCS") codes for each brand of IVIG so that the average sales price ("ASP") for each IVIG product is based on information submitted for that product and thus reflective of each product's unique formulation; and (iii) clarifying that IVIG is a biologic response modifier for purposes of paying for administering the product. These mechanisms are discussed separately below.

A. Add-On

In our comments on the 2006 physician fee schedule proposed rule, we advocated for an add-on payment for IVIG that captures the acquisition, direct and indirect handling costs associated with the product. Although the agency rejected a number of recommended payment adjustments for IVIG, including an add-on payment, because of its belief that ASP data are reflective of hospital acquisition costs for IVIG, it nonetheless determined that Medicare should make an additional payment of about $69 for each administration of IVIG to compensate for preadministration services related to IVIG. 70 Fed. Reg. at 70220.

The IVIG community appreciates the agency's recognition of these types of costs incurred in providing IVIG to beneficiaries, but believes that the additional preadministration payment is insufficient to ensure access to IVIG from physicians and suppliers, particularly in a year in which patients that migrated to hospital outpatient departments may experience less access in that setting and have to return to physicians and suppliers. While the additional payment does reimburse for some of the costs incurred related to IVIG, other costs would remain uncompensated. As we explained in our comment letter related to the proposed rule, the Plasma Protein Therapeutics Association (PPTA) and its member companies with the input of other stakeholders in the IVIG community, commissioned the Lewin Group to develop additional information to detail the costs incur related to IVIG. These data should help us identify the costs that remain uncompensated. Attached is a copy of the findings.

Moreover, we are concerned that the payment for preadministration services is labeled a temporary mechanism only for 2006. 70 Fed. Reg. at 70221. We envision that physicians and suppliers will continue to incur the costs that are compensated through this payment beyond 2006, and thus, it should be a permanent feature, augmented as suggested above to capture a fuller range of costs to furnish IVIG.

B. Expanded HCPCS Codes for IVIG Products

With payment for IVIG determined using the average sale price plus 6% payment methodology, we believe that CMS must take a critical step to ensure that this methodology establishes rates that are appropriate to sustain access to the various IVIG products as they are not interchangeable. Specifically, we believe that each brand name IVIG should have its own HCPCS code so that the ASP-based payment rate will be computed on its own ASP information, yielding rates that are pertinent to each brand, which should enhance access to IVIG products.

The following brands of intravenous immune globulin are now available in the United States market: Polygam® SD, Panglobulin® NF, Gammagard® S.D., Gamunex®, Flebogamma®, Octagam®, Carimune™ NF, and Gammagard® Liquid. Establishing a separate HCPCS codes for each brand is appropriate because there are important clinical differences among them, such as:

- Some brands contain no sugars, which is beneficial for diabetics;
- Some brands have low osmolality and low volume, which physicians sometimes prefer for patients with congestive heart failure or compromised renal function;
- Some brands contain sucrose, which can create a higher risk of renal failure;
- Some brands contain less immunoglobulin A ("IgA"), which is better for patients with IgA deficiencies; and
- Some brands have a lower pH, which may be preferable for patients with small peripheral vascular access or a tendency toward phlebitis.

Physicians prescribe different brands of IVIG due to these differences, yet CMS' coding and payment for these brands does not recognize such differences because there is just one code for liquid IVIG and one code for lyophilized (powder) IVIG. CMS can better assure the accuracy of the payment rates and thus promote access to all brands of IVIG by creating separate codes for each brand of IVIG. Brand specific reimbursement will serve another purpose of the agency as well – gaining an "improved understanding of the contemporary, volatile IVIG marketplace," 70 Fed. Reg. at 70220, by allowing CMS to track the individual brand name products.

According to the final rule the agency issued regarding the hospital outpatient prospective payment system, CMS considered establishing brand-specific HCPCS codes for IVIG, but did not find a "compelling" reason to override the standard practice of not establishing brand-specific codes. 70 Fed. Reg. 68516, 68648 (Nov. 10, 2005). The IVIG community respectfully believes that the Final Rule itself offers compelling reasons to override the standard practice, specifically:

- "we continue to be concerned about reports of patients experiencing difficulties in accessing timely IVIG treatments and reports of providers experiencing difficulties in obtaining adequate amounts of IVIG on a consistent basis to meet their patients' needs in the current marketplace." 70 Fed. Reg. at 70219;
- "The Secretary's Advisory Committee on Blood Safety and Availability has recommended immediate steps be taken to ensure access to IVIG so that patients' needs are being met." Id.;
- "the complexity of the IVIG marketplace makes it unclear what particular systematic approaches would be most effective in addressing the many individual circumstances that have been shared with us while not exacerbating what appears to be a temporary disruption in the marketplace." Id.;
- "Historically, numerous factors, including decreased manufacturer capacity, increased usage, more sophisticated processing steps, and low demand for byproducts from IVIG fractionation have affected the supply of IVIG." Id.;
- An additional payment for preadministration services is needed to "ensure that Medicare beneficiaries depending upon IVIG experience no adverse health consequences from the market instability for IVIG products." 70 Fed. Reg. at 70221; and
- "Based on the potential access concerns, the growing demand for IVIG, and the unique features of IVIG detailed above, as we seek to gain improved understanding of the contemporary volatile marketplace, we will employ a two-pronged approach during CY 2006 to help ensure the availability of IVIG to physicians and hospital outpatient departments." 70 Fed. Reg. at 70220.

We submit that the totality of these statements, in particular the decision to take a two-pronged approach to ensure continued access to IVIG across treatment settings, makes clear that there are compelling reasons to override the standard practice of not establishing brand-specific HCPCS codes. Accordingly, we urge CMS to issue brand-specific codes for IVIG products for use effective January 1, 2006.

C. IVIG Is a Biologic Response Modifier

CMS has incorporated the new Current Procedural Terminology ("CPT") codes to bill for drug administration services in 2006, as it indicated was likely in the proposed rule. Under these new codes, chemotherapy administration codes apply to "substances such as monoclonal antibody agents, and other biologic response modifiers."[1] As a result, when a physician administers a biologic response modifier, even though it may not be "chemotherapy," it is appropriate to bill 96413 for the administration service. The IVIG community urges CMS to clarify, in forthcoming instructions on billing for drug administration services or otherwise, that IVIG is a biologic response modifier and that physicians should bill for administering it under 96413 effective for services furnished on or after January 1, 2006.

Based on the above-quoted language in CPT 2006, any product that is a "biologic response modifier" should be billed under a chemotherapy administration code and IVIG is such a product. According to the U.S National Library of Medicine, biologic response modifier therapy is defined by reference to "immunotherapy," which is categorized as "Treatment to stimulate or restore the ability of the immune system to fight cancer, infections, and other diseases."[2] IVIG is precisely a treatment that restores the ability of the immune system to fight cancer and other diseases – e.g., Kawasaki's disease, chronic lymphocytic leukemia, primary immune deficiency disease, and secondary immune deficiency diseases. Accordingly, we urge CMS to provide written guidance indicating that IVIG is a biologic response modifier for purposes of billing for administering the product.

CONCLUSION

The group of organizations represented below appreciates the opportunity to comment on the Final Rule. We recognize and greatly appreciate CMS' effort and commitment to ensure patient access to IVIG and believe that further measures are needed in order to alleviate this ongoing situation. We are deeply concerned about the impact the Final Rule could have on beneficiary access to a life saving therapy, especially since there are limited other options as a site of care for patients dependent upon IVIG. In this comment letter, we offer three mechanisms to ensure that such beneficiaries will have continued access to IVIG through physicians and suppliers – a permanent and comprehensive add-on payment, establishment of brand-specific HCPCS codes, and recognition of IVIG as a biologic response modifier for purposes of drug administration billing. As explained above, there are ample reasons for CMS to take all three actions effective January 1, 2006.

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[1] CPT 2006 Current Procedural Terminology Professional Edition, at p. 400.
[2] *See* http://ghr.nlm.nih.gov/ghr/glossary/immunotherapy .

We look forward to continuing to work with CMS to ensure continued access to IVIG furnished by physicians and suppliers. Please contact Julie Birkofer at 202-789-3100 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

Guillain-Barré Syndrome (GBS)/Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) Foundation International
Immune Deficiency Foundation (IDF)
Jeffrey Modell Foundation (JMF)
The Neuropathy Association (TNA)
Amerinet
American Academy of Allergy, Asthma and Immunology (AAAAI)
ASD Healthcare, AmerisourceBergen Specialty Group
Baxter BioScience
Cardinal Health
FFF Enterprises, Inc.
Grifols USA Inc.
Octapharma USA
The Plasma Protein Therapeutics Association
Talecris Biotherapeutics
ZLB Behring